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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

JOSEPH KLOBUS and DORA KLOBUS, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. AKERO THERAPEUTICS, INC., ANDREW CHENG, CATRIONA YALE, and WILLIAM WHITE, Defendants.	Case No. 4:24-cv-02534-YGR CLASS ACTION AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. Lead Plaintiffs Joseph Klobus and Dora Klobus ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' Amended Complaint against Defendants, allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of certain United States Securities and Exchange Commission ("SEC") filings, public statements, and press releases by Akero Therapeutics, Inc. ("Akero" or the "Company"), as well as media and financial analyst reports about Akero and the facts alleged herein. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

2. This is a securities class action on behalf of all purchasers of Akero common stock between September 13, 2022 and October 9, 2023, inclusive (the "Class Period"). Plaintiffs seek to pursue claims under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), and Rule 10b-5 promulgated thereunder against: Akero, Andrew Cheng, M.D., Ph.D., Catriona (a/k/a Kitty) Yale, and William White.

3. During the Class Period, Defendants violated §§10(b) and 20(a) of the Exchange Act by making false and misleading statements and omissions concerning one of the Company's key clinical trials for the commercialization of its lead product candidate efruxifermin ("EFX") to provide a new treatment for patients with nonalcoholic steatohepatitis ("NASH"),[1] a serious liver disease. As described herein, while the treatment of ("NASH") may be complex, the allegations are straightforward: Defendants, repeatedly and consistently, represented that their clinical trial enrolled ***only*** patients with biopsy-confirmed NASH, when in fact Akero also enrolled patients with cryptogenic cirrhosis, a distinct medical condition.

[1] Shortly after the Class Period, NASH was renamed metabolic dysfunction-associated steatohepatitis ("MASH"). Mary E. Rinella, et al., *A multisociety Delphi consensus statement on new fatty liver disease nomenclature*, Journal of Hepatology, 1542 (Dec. 2023). The term "NASH" is used herein.

II. JURISDICTION AND VENUE

4. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

5. Jurisdiction is conferred by 28 U.S.C. §§1331 and 1337, and §27 of the Exchange Act, 15 U.S.C. §78aa.

6. Venue is proper in this District pursuant to 28 U.S.C. §1391(b), and §27 of the Exchange Act, 15 U.S.C. §78aa. Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this District.

7. In connection with the acts alleged in this Amended Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES TO THE ACTION

8. Lead Plaintiffs Joseph Klobus and Dora Klobus ("Plaintiffs") purchased or otherwise acquired Akero common stock during the Class Period and suffered damages as a result of the conduct alleged herein.

9. Defendant Akero Therapeutics, Inc. ("Akero") is a Delaware corporation with its principal executive offices located in San Francisco, California. Akero's common stock is listed and publicly traded on the NASDAQ Global Select Market under the ticker symbol "AKRO." Akero is a clinical stage biopharmaceutical company that was founded to develop transformational medicines for patients with serious metabolic diseases that lack effective treatment options. The Company is currently focused on advancing EFX, its lead product candidate, formerly known as AKR-001, to provide a new treatment for patients with NASH, a serious liver disease.

10. Defendant Andrew Cheng, M.D., Ph.D. ("Cheng") has served as Akero's President and Chief Executive Officer ("CEO") and a member of Akero's Board of Directors since September 2018.

11. Defendant Catriona (a/k/a Kitty) Yale ("Yale") has served as Akero's Chief Development Officer ("CDO") since 2018.

12. Defendant William White ("White") has served as Akero's Chief Financial Officer since May 2019.

13. Defendants referenced above in ¶¶10-12 are referred to herein as the "Individual Defendants."

IV. THE INDIVIDUAL DEFENDANTS CONTROLLED AKERO

14. Each of the Individual Defendants was directly involved in the management and day-to-day operations of Akero at the highest levels and was privy to confidential proprietary information concerning Akero and its business, operations, clinical trials, plans, and present and future business prospects. In addition, the Individual Defendants were involved in drafting, producing, reviewing, and disseminating the false and misleading statements and information alleged herein, and were aware of, or recklessly disregarded, the false and misleading statements being issued about Akero and its clinical trials of EFX, and approved or ratified these statements, in violation of the federal securities laws.

15. As officers and controlling persons of a publicly-held company whose securities are registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, which is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate, truthful, and complete information with respect to Akero's operations, business, expenditures, and present and future business prospects, including information concerning Akero's clinical trials of EFX. In addition, the Individual Defendants each had a duty to correct any previously issued statements that were materially misleading or untrue, so that the market price of Akero's publicly traded stock would be based upon truthful, accurate, and complete information. Defendants' false and misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

16. The Individual Defendants, because of their positions of control and authority as officers and/or directors of Akero, were able to, and did, control the contents of various SEC filings, press releases, and other public statements pertaining to Akero and its clinical trials of EFX. Each Individual Defendant was provided with copies of the documents alleged herein to be false and misleading before or shortly after their issuance, participated in conference calls with

investors during which false and misleading statements were made, and had the ability and opportunity to prevent the statements' issuance or cause them to be corrected. Accordingly, each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained therein.

V. BACKGROUND

17. Akero is a clinical-stage biopharmaceutical company developing EFX for the treatment of NASH and NASH-related liver fibrosis and cirrhosis. As reported in Akero's FY22 Form 10-K for fiscal year ending December 31, 2022, filed on March 17, 2023 (the "2022 10-K"), as of February 28, 2023, Akero employed 38 full-time employees.

A. EFX Is Akero's Only Product

18. Akero was incorporated in January 2017, and at all relevant times has had the primary purpose of commercially developing its only clinical asset, EFX. As reported in Akero's 2022 10-K, "we are heavily dependent on the success of EFX, [Akero's] only product candidate."

19. EFX is a protein that was engineered to mimic the effect of fibroblast growth factor 21 ("FGF21"), a naturally occurring human hormone that protects against cellular stress and regulates whole-body metabolism and tissue-specific stress responses. On its website, Akero asserts that "[b]y delivering sustained and balanced signaling through FGF21's receptors in liver and adipose tissue, EFX has the potential to treat [N]ASH by addressing all core drivers of disease progression." EFX was designed to be administered to patients once weekly via subcutaneous injections.

20. NASH is a serious form of nonalcoholic fatty liver disease ("NAFLD") that is estimated to affect 17 million Americans. According to Akero, NASH is primarily driven by chronic excess caloric intake, or ingesting more energy than the body expends over a sustained period, which results in people becoming overweight or obese. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis (mild scarring) that can progress to cirrhosis (severe scarring), liver failure, cancer, and death. A patient that has definitive NASH at baseline must have an NAFLD

activity score[2] of greater than or equal to 3, with a score of at least 1 in each of the components of steatosis, ballooning, and inflammation. Approximately 20% of NASH patients will progress to cirrhosis, which has a higher risk of mortality – approximately 50% 5-year mortality rate without a liver transplant.

21. At all times relevant to this action, no drugs had been approved by the United States Food and Drug Administration ("FDA") for the treatment of NASH, representing a critical unmet need in the field of liver disease. The FDA only recognized liver transplants as an effective treatment for cirrhosis due to NASH.

22. Over the past several years, Akero has designed and conducted a series of clinical trials to test the efficacy and safety of EFX in treating NASH patients. Akero tested EFX in different NASH populations. Some trials targeted NASH patients with more severe symptoms (*i.e.*, those with NASH-induced cirrhosis), while other trials targeted NASH patients with less severe symptoms (*i.e.*, those who were pre-cirrhotic). As explained in the 2022 10-K, Akero's cirrhotic versus pre-cirrhotic dividing line comports with the FDA guidance published in 2018 and 2019, that considers pre-cirrhotic NASH and cirrhotic NASH as two separate indications for treatment purposes.

23. Thus, relevant to determining whether a patient was eligible to participate in a particular study (or cohort of a study), Akero first needed to confirm that the patient suffered from NASH and next needed to determine whether the patient was pre-cirrhotic or suffering from NASH-induced cirrhosis.

24. The most reliable diagnosis and staging of NASH is achieved by examining a liver biopsy specimen under a microscope. A liver biopsy, however, is an invasive procedure involving the extraction of a liver tissue sample. Further complicating matters, liver biopsies have been associated with occasionally causing morbidity (the state of being unhealthy for a particular disease) and, in rare circumstances, mortality. As a result, the use of liver biopsies in clinical trials

[2] The NAFLD activity score is a histological scoring system used to evaluate and measure the spectrum of the disease.

poses significant logistical challenges (including cost and the availability of pathologists with specific expertise in NASH), and many patients are reluctant or unwilling to undergo the procedure given its invasive nature and attendant risks – concerns that the COVID-19 pandemic only exacerbated.

25. Non-invasive biomarkers are sometimes used to diagnose or assess the various grades of NASH and stages of liver fibrosis. For example, a liver elastography through a FibroScan, a special ultrasound technology that measures liver stiffness (hardness) and fat changes in the liver, is sometimes used in conjunction with the following scale:

- A fibrosis score of F0 to F1 (2 to 7 kilopascals ("kPa")) means there is little or no scarring on the liver.
- A fibrosis score of F2 (7.5 to 10 kPa) indicates moderate scarring that has spread outside the liver.
- A fibrosis score of F3 (10 to 14 kPa) indicates severe scarring which has spread and disrupts normal blood flow.
- A fibrosis score of F4 (14 kPa or higher) means late-stage scarring or cirrhosis, where the scarring is permanent and the damage is irreversible.

Under this scale, the F0-F3 grades correspond to pre-cirrhotic patients with increasing levels of fibrosis, while the F4 grade corresponds to patients for whom fibrosis has advanced to cirrhosis.

26. Cirrhosis has two different clinical stages: compensated and decompensated. Compensated cirrhosis is the asymptomatic stage and corresponds to Child-Pugh score A.[3] Decompensated cirrhosis is the symptomatic stage that is characterized by the presence or development of overt complications such as ascites, jaundice, variceal hemorrhage, or hepatic encephalopathy and corresponds to Child-Pugh score B or C. Due to the high mortality rates in classes B and C patients, Akero only enrolled class A patients in trials with cirrhotic patients. For compensated cirrhosis patients, non-invasive parameters may all be normal and therefore a liver biopsy is required for the most accurate diagnosis.

[3] The Child-Pugh Score is a scoring system used to determine the degree of liver failure present in patients with cirrhosis. Under the Child-Pugh system, the three classes correlate with one- and two-year patient survival: (i) class A: 100% and 85%; (ii) class B: 80% and 60%; and (iii) class C: 45% and 35%.

B. NASH-Induced Cirrhosis and Cryptogenic Cirrhosis Are Different Conditions

27. Significantly, cirrhosis has multiple potential origins. Cirrhosis can be caused by alcohol abuse, hepatitis, and nonalcoholic fatty liver disease (including its NASH subtype). When the cause of a patient's cirrhosis is unknown, the condition it is referred to as "cryptogenic" cirrhosis – *i.e.*, cirrhosis "of obscure or unknown origin."

28. Cryptogenic cirrhosis is treated differently from NASH cirrhosis by medical experts. For example, in a *Journal of Hepatology* article titled "Is cryptogenic cirrhosis different from NASH cirrhosis?" the authors concluded: "Based on risk perspectives, [cryptogenic cirrhosis] should not be equated with the term 'NASH cirrhosis.'" Their conclusion was based on a comparison of the clinical characteristics of thousands of adults with cryptogenic cirrhosis (n=7,999) to those with cirrhosis caused by NASH (n=11,302), alcohol (n=21,714), and autoimmune hepatitis (n=3,447). As further explained by the authors: "We hypothesized that cryptogenic cirrhosis is a distinct condition from cirrhosis caused by . . . NASH. By comparing cryptogenic cirrhosis with cirrhosis of other causes, we found clear clinical differences. Therefore, cryptogenic cirrhosis should not be considered the same as NASH cirrhosis."

29. In the FDA's 2019 draft guidance for industry titled "Nonalcoholic Steatohepatitis with Compensated Cirrhosis: Developing Drugs for Treatment Guidance for Industry," the FDA cautioned sponsors of drugs designed to treat compensated NASH cirrhosis against including cryptogenic cirrhosis patients in trials. The guidance stated: "Sponsors should be careful to enroll in clinical trials only patients whose cirrhosis is secondary to NASH and not caused by other etiologies. Patients should have histological diagnoses of NASH, and other causes of chronic liver disease should be ruled out."

30. The distinction between NASH-induced cirrhosis and cryptogenic cirrhosis comes with an important difference. Patients suffering from cryptogenic cirrhosis often have a more advanced (severe) form of cirrhosis and therefore have a different risk profile. Additionally, EFX's mechanism of action may not work in patients whose cirrhosis was caused by something other than NASH.

C. Defendants Prioritized the Massive Market Opportunity in the Treatment of F4 Cirrhosis Due to NASH

31. With no FDA-approved drugs for the treatment of NASH, there was a vast market opportunity for any company that could successfully get a NASH drug approved by the FDA. For example, on October 3, 2022, Jefferies issued a report titled "Mgmt Meetings: Could Be Quicker Phase III + Only Co with Strong Fibrosis Data," describing the "blockbuster potential in the multi-billion dollar NASH space." And, during the Class Period, Defendants themselves consistently described the "[s]ubstantial potential market opportunity" for NASH treatments and described EFX as a "Potential First-in-Class & Best-in-Class NASH Drug."

32. Defendants' stated goal was to prioritize trials that would show EFX improves (reduces) fibrosis in the F4 cirrhotic population as a primary endpoint, with the resolution of NASH as a secondary endpoint, because that is where the largest market opportunity was. For example, on May 11, 2022, Yale participated in the Bank of America Healthcare Conference, during which she explained:

> ***[I]t's about being reimbursed***. And so when we think about payers and insurance, ***the F4 patient population, we believe, will definitely be prioritized in terms of the market and reimbursed appropriately so***.
>
> * * *
>
> [W]hen I look at the design of our trials, ***we have been very focused on this fibrosis endpoint [i.e. F4]***. So there's two FDA acceptable histology endpoints for NASH currently. So you can either [aim] for a NASH resolution with no worsening of fibrosis or you could ***focus on fibrosis improvement***, no worsening of NASH. And ***we are obviously focused on the latter***. And the reason really for that is we really believe that ***that's where the payers are really focused*** and there's data really correlating that one-stage improvement with fibrosis with long-term clinical outcomes. And I think ***that's where you're going to get the payers to buy in and really look at reimbursement*** based on the long-term clinical outcome improvements, which is just not so clear whether if you just achieved a NASH resolution endpoint.

33. The market understood these financial incentives. For example, during the Class Period, analysts covering the Company reported there was a "market opportunity" of "$20B" for EFX, based, in significant part, on the "potential for EFX in the NASH cirrhotic (F4) setting" and that "the F4 fibrosis segment (NASH patients who have compensated cirrhosis) is the biggest commercial opportunity for a NASH drug."

D. Akero Needed to Raise Millions of Dollars to Conduct and Complete Clinical Trials of EFX

34. With EFX as its only drug candidate, since its inception Akero suffered recurring losses and needed to raise significant capital to fund its clinical trials program and the commercialization of EFX. As of at least September 2022, analysts understood that Akero's focus "moving forward will be on cash runway[;] how [Akero management] will consider funding for a Phase III [clinical trial of EFX]" and that "[l]arge cash infusions will be required to get this drug to the finish line."

35. Akero addressed the need to raise funds primarily through public offerings of its common stock. During a November 29, 2022 Evercore ISI ("Evercore") HealthCONx Conference attended by Tim Rolph ("Rolph"), Akero's Chief Scientific Officer and Co-Founder, Cheng, and Yale, Cheng explained Akero relied on raising money from investors to fund drug trials for EFX.

36. To that end, during the Class Period Akero conducted three offerings of common stock via 424(b) prospectuses, raising gross proceeds of $230 million in a September 2022 offering of more than 8.8 million shares at $26 per share (including the underwriters' full exercise of their option to purchase additional shares), raising gross proceeds of $220 million in a May 2023 offering of more than 5.2 million shares at $42 per share, and raising an additional $127 million in an at the market ("ATM") offering of common stock in March and April 2023, by selling over 3 million Akero shares at an average price of $42.38 per share. In the aggregate, Akero raised at least $577 million in gross offering proceeds from these stock offerings over a 13-month period.

E. Prior to and During the Class Period, Defendants Touted the Similar Design of Akero's Previous Drug Trials and the Ongoing SYMMETRY Trial

37. Potential new treatments go through several phases of drug trials before they can be approved by the FDA, with each phase having a different purpose. Phase 1 trials test a drug in a small group of people (usually 15-50 patients) for safety and to identify side effects. Phase 2 trials test a drug in a larger group of people (usually fewer than 100 patients) to confirm the drug's effectiveness and further study its safety. Phase 3 trials test a drug in a larger group of people (usually hundreds or thousands of patients) to confirm the drug's effectiveness, monitor side

effects, compare it with standard or similar treatments (if applicable), and collect information that will allow the new drug to be used safely.

38. Enrolling patients is essential to any trial. As Akero acknowledged in SEC filings during the Class Period: "Identifying and qualifying patients to participate in clinical trials is critical to our success." Enrolling patients necessarily becomes more difficult as a company advances through the trial phases and more patients are required. This is especially true for smaller patient populations, such as the F4 patient population, compared to, for example, the larger F2 population.

39. Because F4 cirrhosis due to NASH is difficult to treat, and because it is difficult to enroll enough F4 patients for trials requiring biopsies, the track record of companies trying to bring treatments for F4 NASH was marked by failure. On August 9, 2023, in a report titled "AM Q&A with AKRO re:SYMMETRY, updated OUTLOOK," Evercore reported that, for companies attempting to treat cirrhosis: "History has not been kind . . . – it has been a graveyard." And as Jefferies explained in a September 12, 2023 report titled "Preview into F4 Cirrhosis NASH Data + Mgmt Meetings . . . Raise PT to $74": "Historically, F4 had many notable failures, and no drug has shown stat[istically] sig[nificant] fibrosis benefit."

40. Akero conducted three relevant EFX trials before and during the Class Period: The BALANCED, HARMONY, and SYMMETRY studies.

41. In March 2021, before the Class Period, Akero reported results for a clinical trial in which the Company tested EFX in patients with cirrhotic NASH (the Cohort C Expansion of Akero's Phase 2a BALANCED study). Akero's reported results did not include any mention of patients with cryptogenic cirrhosis.

42. During the Class Period, Akero stated that it was evaluating EFX in two Phase 2 clinical trials in patients with ***biopsy-confirmed NASH***: (i) Akero's HARMONY trial that tested EFX in ***pre-cirrhotic NASH patients***;[4] and (ii) Akero's SYMMETRY trial that purportedly tested EFX in ***patients with NASH-induced cirrhosis***.

[4] The HARMONY trial was officially titled "A Phase 2b, Randomized, Double-Blind, Placebo Controlled Study Evaluating the Safety and Efficacy of Efruxifermin ***in Non-Cirrhotic Subjects***

43. The SYMMETRY study was officially titled "A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Efruxifermin in ***Subjects With Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH)***." Akero described the 96-week SYMMETRY study as a multi-center, randomized, double-blind, placebo-controlled clinical trial that enrolled 182 patients ***with biopsy-confirmed compensated cirrhosis*** (F4), Child-Pugh class A, ***due to NASH***, each of whom received once-weekly subcutaneous injections of 28 milligrams of EFX, 50 milligrams of EFX, or placebo.[5] Defendants' descriptions of SYMMETRY gave the impression that patients with cryptogenic cirrhosis were excluded from the study.

44. Every clinical trial must be conducted according to a clinical trial protocol which is "[a] document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents." U.S. Dep't of Health & Hum. Servs., *E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry*, §1.44 (Mar. 2018). The sponsor of the clinical trial, here Akero, is responsible for designing the protocol. *Id.*, §5.4.1. The trial's protocol is to include, *inter alia*, patient inclusion and exclusion criteria, a specific statement of the endpoints to be measured during the trial, and a description of the statistical methods to be employed." *Id.*, §§6.4, 6.5.1-6.5.2, 6.91.

45. The SYMMETRY trial was initiated in July 2021, with a primary efficacy endpoint specified as the proportion of patients who achieved ≥ 1 stage improvement in fibrosis and no worsening of NASH, based on liver biopsies collected at week 36 versus baseline. More than two

With Nonalcoholic Steatohepatitis (NASH)." The 96-week Phase 2b HARMONY study was a multi-center, randomized, double-blind, placebo-controlled clinical trial that enrolled 128 biopsy-confirmed NASH patients with fibrosis stage 2 or 3 (F2 or F3) who each received once-weekly subcutaneous dosing of 28 milligrams of EFX, 50 milligrams of EFX, or a placebo. On the first day of the Class Period, Akero published a readout of data collected through week 24 of the study. Thereafter, HARMONY trial patients continued to receive EFX or placebo for up to 96 weeks to provide additional data.

[5] The SYMMETRY study added a separate expansion cohort, known as Cohort D, which evaluated the safety and tolerability of EFX compared to placebo when added to an existing glucagon-like peptide ("GLP-1") receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes ("Cohort D"). Unless indicated otherwise, references to the SYMMETRY study herein are to the main SYMMETRY study and not to Cohort D.

years later, on October 10, 2023, Akero published a readout of data collected through week 36 of the trial (based on a second liver biopsy). SYMMETRY trial patients continue to receive EFX or placebo for up to 96 weeks to provide additional data, including through a second on-treatment biopsy (third overall) at week 96.

46. After the sponsor designs the protocol, the sponsor ultimately provides it to the trial's investigators who agree to be bound by its terms when testing patients. Specifically, "[t]he investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and which was given approval/favorable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement." *Id.*, §4.5.1. For example, Yale signed the protocol governing Akero's Phase 2a BALANCED study, which included a representation directly above her signature: "This clinical study protocol was subject to critical review and has been approved by the Sponsor."

47. The SYMMETRY study was designed, and touted to investors, as an expansion of the BALANCED Cohort C study in patients with cirrhotic NASH. During an October 12, 2021 call, for example, Rolph emphasized that "Cohort C" of the BALANCE study "is the first study really to show any significant movement in . . . that [F4/NASH] population," which "really motivated us to go forward in a Phase 2b study . . . dedicated to this population, and that's the SYMMETRY" trial. Rolph described EFX as "set[ting] the benchmark" for NASH treatment based on the BALANCED study results, and distinguished Akero's trials from competitor 89bio's drug trial, which was being tested "***not*** in NASH patient – NASH confirmed patients."

48. Similarly, during a September 13, 2022 call, Cheng represented that Cohort C "strengthens our confidence that we may continue to see favorable results in our ongoing Phase 2b SYMMETRY study ***in patients with cirrhotic NASH***, which we expect to read out next year."

49. As Akero approached the 36-week SYMMETRY readout Cheng mentioned, Defendants continued to describe SYMMETRY as designed in the same way as the BALANCED and HARMONY trials. For example, on January 10, 2023, Cheng stated that "***like HARMONY***,

it's a randomized, double-blind, placebo-controlled trial. ***SYMMETRY only [involves] patients with biopsy-proven NASH***, F4."

50. In turn, the market viewed the SYMMETRY study as having been designed in the same way as the Cohort C and HARMONY studies, *i.e.*, in patients with biopsy-confirmed NASH, and reasoned that SYMMETRY was likely to show similar results. For example, in a September 12, 2023 Jefferies report titled "Preview into F4 Cirrhosis NASH Data + Mgmt Meetings . . . Raise PT to $74," analysts noted that "[t]he F4 study [SYMMETRY] is designed similarly vs the Phase IIb in F2/3 [HARMONY]" and would show statistically significant results "if it were to show results similar to the earlier [BALANCE] Cohort C numbers."

51. The SYMMETRY study was essential to Akero's ability to win approval for EFX as a treatment for F4 cirrhotic NASH patients. On November 17, 2022, during a call with Jefferies, Cheng was asked "if that decision tree [for how to get FDA approval of EFX] changes if the symmetry study is not so great," he replied: "Yep." And as H.C. Wainwright noted in a detailed August 14, 2023 report titled "2Q Recap; SYMMETRY Data in Cirrhotic Patients On Target in 4Q23; Initiations of SYNCHRONY Studies in 2H23; Affirm Buy":

> ***SYMMETRY is a key component of EFX's NASH regulatory path***. On August 11, Akero announced that Week 36 data readout from the Phase 2b SYMMETRY main study of efruxifermin (EFX) in ***adult cirrhotic NASH*** patients (F4, compensated) remains on track for 4Q23. Recall, the SYMMETRY main study (NCT05039450) ***enrolled 182 compensated cirrhotic NASH patients***, randomized to receive once-weekly subcutaneous dosing of EFX 28 mg, EFX 50 mg, or placebo. . . . Given that the FDA and EMA[6] both regard fibrotic NASH and cirrhotic NASH ***as two wholly separate and distinct indications***, we believe that Akero may opt to pursue the FDA's alternative NASH approval pathway if SYMMETRY top-line results are sufficiently positive. . . . As such, ***we regard SYMMETRY's Week 36 data readout in 4Q23 as a major milestone for EFX and Akero, as positive data would support EFX's advancement into a Phase 3 study in F4 NASH. Affirm Buy***.

52. The SYMMETRY study was essential not only to Akero's ability to win approval for EFX as a treatment for F4 cirrhotic NASH patients, but also to its ability to timely complete the HARMONY study in F2/F3 patients and follow-on Phase 3 trials in the same patient population. Notably, Akero could potentially avoid a drawn-out HARMONY study of long-term

[6] The European Medicines Agency ("EMA") is the European Union's equivalent of the FDA.

outcomes and pursue accelerated approval of the F2/3 population if it showed success in the F4 population through SYMMETRY. As Jefferies stated in an October 3, 2022 report titled "Mgmt Meetings: Could Be Quicker Phase III + Only Co with Strong Fibrosis Data": "We think the largest piece of the puzzle at the moment is how AKRO will show the long-term outcomes if FDA requires them for the F2/3 population [*i.e.*, HARMONY]. One way around this is to study outcomes in an F4 population [*i.e.*, SYMMETRY] ***to support the F2/3 accelerated approval***." Jefferies concluded "this obviously hinges on F4 data H2:23 [*i.e.*, the 36-week SYMMETRY readout in October 2023] and the degree of benefit shown there."

VI. SUMMARY OF ALLEGATIONS

A. Throughout the Class Period, Defendants Misrepresented the Design and Enrolled Patient Population of the SYMMETRY Trial

53. Throughout the Class Period, Defendants consistently represented to investors that they designed Akero's SYMMETRY drug trial to study EFX in patients with cirrhosis ***due to NASH***. For example, at all relevant times, Akero's website, on the "Clinical Trials" page, described "[t]he Phase 2b SYMMETRY study [a]s a multicenter, randomized, double-blind, placebo-controlled, clinical trial ***in biopsy-confirmed NASH*** patients with compensated cirrhosis (F4), Child-Pugh class A."

54. The Class Period begins on September 13, 2022, when Defendants reported the 24-week HARMONY readout of trial results in a Form 8-K release and then in a Phase 2b HARMONY Trial Data Presentation. In the Form 8-K, Defendants misleadingly described Akero's SYMMETRY study as "***a Phase 2b trial in biopsy-confirmed NASH*** patients with compensated cirrhosis, Child-Pugh class A" and "***the SYMMETRY study in patients with cirrhotic NASH*** (F4 fibrosis, compensated)." And in the presentation, Yale emphasized that the HARMONY study provided the "foundation" for the SYMMETRY trial, as the improvements in the pre-cirrhotic NASH patients in the former were "potentially favorable" signs for the purportedly similar population of "***patients with cirrhotic NASH***" in the SYMMETRY trial.

55. As discussed below, ¶¶92-93, each of Defendants' material misrepresentations and omissions above concerning the design and enrolled patient population of the SYMMETRY trial

was materially false and misleading when made as Defendants knew or deliberately disregarded and failed to disclose the following adverse facts:

(a) that approximately 20% of the patients enrolled in the SYMMETRY study did not have biopsy-proven compensated cirrhosis due to NASH; those patients had cryptogenic cirrhosis, which is not the same as and should not be equated with "NASH cirrhosis" (*see* ¶¶158-159, 161);

(b) that it was "prespecified" in Akero's SYMMETRY trial design to include patients with cryptogenic cirrhosis, a fact Defendants have admitted to discussing with the FDA, confirming their knowledge of this patient subset (¶¶161-162);

(c) that it was further "prespecified" in Akero's SYMMETRY trial design to exclude patients with cryptogenic cirrhosis from the calculation of the NASH resolution secondary endpoints. The protocol's recognition of the need for separate data sets itself made clear to Defendants that the inclusion of cryptogenic cirrhotics was material to both the trial and the market (¶¶155-157, 161-162);

(d) that the SYMMETRY study did not align with FDA guidance for testing a drug in treating NASH cirrhotics because Akero had not ruled out potential causes of each patient's cirrhosis other than NASH (¶¶29, 77, 158);

(e) that, as a result of the inclusion of cryptogenic cirrhotics in the SYMMETRY study and in the calculation of the study's primary endpoint, Akero introduced a confounding factor into the study's design, materially influencing the study's potential results and increasing the risks that the study would fail to meet its primary endpoint (¶¶155-57, 160-161, 165-166); and

(f) that, as a result of (a)-(e) above, Defendants materially misrepresented the nature of the SYMMETRY trial, its usefulness in supporting any new drug application filed by Akero seeking approval for treatment of cirrhotic NASH patients, the likelihood that the SYMMETRY trial would be successful as measured by its primary endpoint, and the likelihood that EFX would become a commercial treatment for NASH cirrhotics.

56. After the September 13, 2022 HARMONY readout and throughout the Class Period, Defendants – in SEC filings, press releases, and presentations to investors – continued to describe the SYMMETRY trial design in the same misleading way, as only involving patients with biopsy-confirmed NASH.

57. Defendants' false and misleading statements concerning the composition of patients in the SYMMETRY trial were repeated in 424(b) prospectuses in order to raise substantial operating funds for Akero, including in: (i) a September 15, 2022 prospectus supplement filed with the SEC for a secondary offering of Akero common stock (the "September 2022 Prospectus") that ultimately raised gross proceeds of $230 million; (ii) a March 17, 2023 prospectus supplement filed with the SEC in connection with an ATM stock offering that ultimately raised gross proceeds of at least $127 million (the "March 2023 ATM Prospectus"); and (iii) in a May 17, 2023, prospectus supplement filed with the SEC in connection with a secondary offering of common stock (the "May 2023 Prospectus") (collectively, the "Prospectuses") that ultimately raised gross proceeds of $220 million.[7]

58. The September 2022 Prospectus, March 2023 ATM Prospectus, and May 2023 Prospectus affirmed and amplified Defendants' earlier misrepresentations about SYMMETRY's trial design by representing: SYMMETRY was evaluating "***patients with cirrhotic NASH*** (F4 fibrosis, compensated)"; SYMMETRY was a "Phase 2b clinical trial of EFX in ***patients with NASH who have cirrhosis*** (F4 fibrosis, compensated)"; and "EFX is currently being evaluated in two Phase 2b clinical trials in ***patients with biopsy-confirmed NASH***: [one of which is] the ***SYMMETRY study in patients with cirrhotic NASH*** (F4 fibrosis, compensated)."

59. The Prospectuses also contained false and misleading risk warnings that omitted to disclose the warned-of risks had already come to pass. For example, they purported to warn that identifying and enrolling patients with NASH in clinical trials "could" be difficult: "***Enrollment and retention of patients in clinical trials*** is an expensive and time-consuming process and ***could***

[7] The Prospectuses listed in this paragraph were all supplements to a previously filed May 18, 2021 prospectus.

be made more difficult or rendered impossible by multiple factors outside our control, including ***difficulties in identifying patients with . . . NASH***."

60. The September 2022 Prospectus, in incorporating by reference the Company's annual report for fiscal year ending December 31, 2021, filed February 25, 2022 on Form 10-K, and signed by Cheng and White ("2021 10-K"), further warned that:

> Identifying and qualifying patients to participate in clinical trials is critical to our success. We may encounter delays in enrolling or be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study . . . . In particular, as ***a result of the inherent difficulties in diagnosing NASH*** and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. ***This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we are enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study and subsequent clinical trials***.

61. Notably, the March 2023 ATM Prospectus and May 2023 Prospectus, by incorporating by reference the 2022 10-K, rather than the 2021 10-K, modified that warning, removing the reference to "only" enrolling patients with biopsy-confirmed NASH:

> Identifying and qualifying patients to participate in clinical trials is critical to our success. We may be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study. . . . In particular, as ***a result of the inherent difficulties in diagnosing NASH*** and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all.

62. Such warnings were false and misleading, for all of the reasons described below (¶107), including because Defendants omitted that they were enrolling patients with cryptogenic cirrhosis, and therefore the risk that Akero might face difficulties identifying, diagnosing, or enrolling, *inter alia*, "only" patients with biopsy-confirmed cirrhosis due to NASH had already materialized.

63. In the aggregate, Akero raised at least $577 million in gross offering proceeds from these stock offerings related to the Prospectuses over a 13-month period.

64. Defendants repeated substantially identical representations concerning the SYMMETRY study patient population, and repeated substantially identical risk warnings, in many

of Akero's other SEC filings throughout the Class Period – including each of the Company's quarterly and annual financial reports.[8]

65. Defendants similarly misrepresented SYMMETRY's trial design in a series of press releases identifying trial milestones. For example, on December 21, 2022, Defendants announced Akero had completed enrollment of the SYMMETRY study. In the press release, Defendants continued to misleadingly describe the SYMMETRY trial as having enrolled "***biopsy-confirmed NASH patients*** with compensated cirrhosis (F4, Child-Pugh class A)." So too Akero misrepresented the SYMMETRY patient population in a press release issued December 8, 2022, announcing that EFX had been designated a breakthrough therapy by the FDA, and in a press release on March 29, 2023, announcing the Company had met with the FDA concerning its Phase II and Phase III trials, including SYMMETRY.

66. Significantly, Defendants also chose to speak to investors on calls and in presentations throughout the Class Period, including at conferences hosted by financial analysts. In doing so, Defendants continued to describe the SYMMETRY trial patient population in the same false and misleading ways. For instance, during a January 10, 2023 presentation at the J.P. Morgan Healthcare Conference, Cheng stated "like HARMONY, it's a randomized, double-blind, placebo-controlled trial. ***SYMMETRY only [involves] patients with biopsy-proven NASH***, F4." And as part of his presentation, Cheng presented a slide deck affirming the statements he made about the SYMMETRY trial. One slide title confirmed "***SYMMETRY Trial Design: Cirrhosis Due to NASH*** (F4)" and listed ***only*** "***F4 NASH***" as a "Key Inclusion Criteria" for participating patients. ¶77.

67. The market found Defendants' description of the SYMMETRY trial design important. On January 10, 2023, J.P. Morgan, the host of the January 10, 2023 conference, reported in their "Takeaways from JPM Healthcare '23": "***Importantly, SYMMETRY only enrolls patients with biopsy proven NASH***." A number of analysts also reproduced the slide Cheng

[8] The additional filings included the November 4, 2022 quarterly report for 3Q22; the March 17, 2023 annual report for FY22; the May 15, 2023 quarterly report for 1Q23; and the August 11, 2023 quarterly report for 2Q23.

presented concerning the "Key Inclusion Criteria" for the SYMMETRY trial, including Morgan Stanley ("Adding as a Top Pick Ahead of Ph2b SYMMETRY Data 4Q23," June 11, 2023), Evercore ("AM Q&A with AKRO re:SYMMETRY, updated OUTLOOK," August 9, 2023), and Jefferies ("Preview into F4 Cirrhosis NASH Data + Mgmt Meetings . . . Raise PT to $74," September 12, 2023).

68. On June 5, 2023, Defendants repeated substantially similar misstatements in a presentation they hosted for the Cohort D readout titled "Akero Phase 2b SYMMETRY Cohort D Data Presentation," and at the September 12, 2023 Morgan Stanley Global Healthcare Conference. In his presentation at the September 12, 2023 conference, Cheng described the SYMMETRY trial while again omitting information concerning the inclusion of cryptogenic cirrhotics among the study's patient population, stating:

> ***So this trial is a very straightforward Phase IIb trial***. It's 182 patients, randomized 1:1:1 to placebo 28 milligrams, of efruxifermin of 50 milligrams. ***These are patients with biopsy-confirmed NASH. That is that they have F4 NASH, they're cirrhotic*** and they're Child-Pugh Class A. These patients, also known as compensated cirrhotics, they're dosed for 36 weeks. And the primary endpoint is one stage improvement in fibrosis without worsening of NASH. And we're also looking at key secondary endpoints such as NASH resolution and a number of other biomarkers.

69. For the reasons below (¶¶92-93, 107), each of Defendants' statements was materially false and misleading when made as Defendants knew or deliberately disregarded and failed to disclose adverse facts including, *inter alia*, that approximately 20% of the patients enrolled in the SYMMETRY study had cryptogenic cirrhosis, which is not the same as and should not be equated with "NASH cirrhosis."

70. Defendants' false and misleading statements concerning the design of the SYMMETRY trial caused Akero's stock price to trade at artificially inflated prices as high as $58.38 on June 13, 2023.

B. Defendants Report SYMMETRY Readout, Reveal for First Time the True Design of the SYMMETRY Trial

71. In anticipation of the October 2023 SYMMETRY readout, analysts continued to report the same understanding of the patient population only including patients with F4 cirrhosis due to NASH, including Jefferies ("Preview into F4 Cirrhosis NASH Data + Mgmt Meetings . . .

Raise PT to $74," September 12, 2023), Cantor Fitzgerald ("Latest Investor Feedback & Poll Results on Different Efficacy Scenarios for AKRO F4 NASH Readout", October 3, 2023) and H.C. Wainwright ("Phase 2b HARMONY Dataset Provides Exhaustive Review of EFX; Phase 2b SYMMETRY Top-Line Readout This Month; Affirm Buy," October 5, 2023).

72. Further, as the October 2023 SYMMETRY readout approached, analysts also noted their increasing confidence that the readout would report positive results. For example, in a September 12, 2023 report titled "Preview into F4 Cirrhosis NASH Data + Mgmt Meetings . . . Raise PT to $74," Jefferies, following a meeting with Akero's management, raised its price target for Akero common stock from $60 to $74 per share "***given confidence***" in the upcoming SYMMETRY readout.

73. On October 10, 2023, Akero held a call (the "October 10, 2023 Call"), led by Cheng, White, and Yale, with investors and analysts to discuss the SYMMETRY trial's results. During the October 10, 2023 call, Defendants confirmed what they previously concealed from investors regarding the makeup of the patient population in the SYMMETRY trial: that It had included patients with cryptogenic cirrhosis and – not ***only*** patients with biopsy-confirmed NASH. In her prepared remarks, Yale explained the discrepancy in pertinent part as follows:

> [G]ood morning, everybody. I'd like to begin with a review of the design of the SYMMETRY study, which is shown on Slide 6.
>
> The SYMMETRY study is a Phase IIb randomized, double-blind, placebo-controlled, multicenter dose-ranging trial. ***All patients had*** biopsy-proven compensated cirrhosis fibrosis Stage 4 due to definitive NASH ***or cryptogenic cirrhosis, presumed secondary to NASH***.
>
> ***Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population***.
>
> * * *
>
> This study enrolled patients with advanced liver disease, ***including patients with either cryptogenic cirrhosis or definitive NASH. The analysis set for NASH resolution endpoints excluded those with cryptogenic cirrhosis who didn't meet definitive NASH at baseline.*** That is the NAFLD activity score of greater than equal to 3, with a score of at least 1 in each of the components of steatosis, ballooning and inflammation.
>
> Consequently, the analysis set for NASH resolution is [comprised] of 126 patients, with 46, 38 and 42 patients, respectively, in the placebo, 28 milligram, and 50 milligram dose groups.

> Cryptogenic cirrhosis is sometimes referred to as burn-type NASH, and is associated with advanced fibrosis and a higher level of risk in terms of liver decompensation or death.

74. During the question-and-answer session of the October 10, 2023 Call, analysts pressed the Company on the inclusion of cryptogenic cirrhotics in the study, recognizing that the information was new and that the inclusion of these patients was a confounding factor in the results. For example, a J.P. Morgan analyst asked:

> And then, this potential for cryptogenic NASH, I think, is a ***new*** variable in thinking about the context of an F4 study. I guess, what's sort of – to the extent there are – any measures that could be tak[en] in a Phase III program to sort of ***reduce their participation and perhaps get a clearer signal?***

75. In response, Cheng acknowledged the different risk profile for cryptogenic cirrhotics, and further, that Akero might need to remove cryptogenic patients from a Phase III trial:

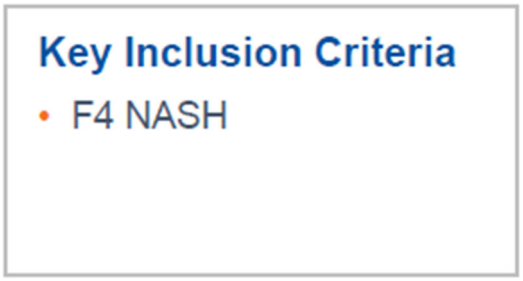
> In terms of cryptogenic cirrhosis, I think these patients represent a part of the cirrhotic spectrum . . . and I think we've – and in consultation with the FDA, have chosen to limit the patients to about 20% of the population. . . . And I think that's something we may consider to do. But of course, that's pending discussions with the agency, which we haven't had.

76. Similarly, an Evercore analyst asked: "[W]as it prespecified to take out the cryptogenic NASH patients?" and, when she did not get a direct answer from Cheng, again asked, "And then just final question was on the cryptogenic cirrhotics. Was it prespecified to exclude them from some of the analysis? Or what was the plan there?" Yale then answered, admitting "***Yes, that was all prespecified***," thus confirming Defendants' knowledge or reckless disregard of the true facts concerning the SYMMETRY study's patient population despite the fact that this information was contrary to what Defendants had told investors regarding the trial's design.

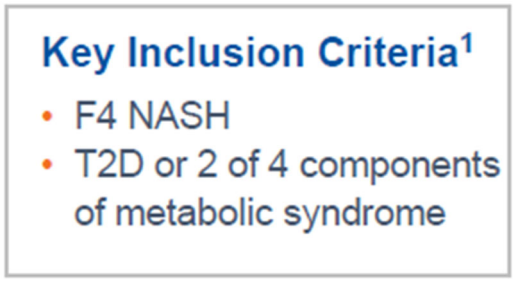
77. During the October 10, 2023 Call, Defendants also made repeated reference to the slideshow attached to a Form 8-K filed earlier that day. The slideshow contained the same slide titled "SYMMETRY Trial Design: Cirrhosis Due to NASH (F4)" as the January 10, 2023 slide. ¶66. But the October 10, 2023 slide contained two significant additions to the "Key Inclusion Criteria" for the study. The first addition was that, while the January 10, 2023 slide listed only "F4 NASH" as a criteria, the October 10, 2023 slide newly added "T2D or 2 or 4 components of metabolic syndrome" as a second criteria. The second difference is that the October 10, 2023 slide

newly added a footnote, which confirmed what Defendants told investors during the October 10, 2023 call, that "[a]ll patients had biopsy-proven compensated cirrhosis (fibrosis stage 4) due to definitive NASH or cryptogenic cirrhosis presumed secondary to NASH. Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population." Defendants' modification of the SYMMETRY patient inclusion criteria is apparent in a side-by-side comparison of the slides:

January 10, 2023 slide



October 10, 2023 slide



[1] All patients had biopsy-proven compensated cirrhosis (fibrosis stage 4) due to definitive NASH or cryptogenic cirrhosis presumed secondary to NASH. Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population.

78. Following these disclosures, the price of Akero stock declined 62.6% from a close of $48.54 on October 9, 2023, to a close of $18.15 on October 10, 2023, on 31.9 million shares traded, up from just 631,600 shares traded on October 9, 2023. The stock price fell another 17% on October 11, 2023, to a close of $15.04 on 10.29 million shares traded on October 11, 2023.

79. Multiple analysts took particular issue with the previously undisclosed inclusion of cryptogenic cirrhotics in the trial. For instance, Cantor Fitzgerald issued two reports on October 10, 2023 – one before the SYMMETRY readout, and one after. In the earlier report, titled "Efruxifermin F4 NASH Trial Readout: Missed Primary But Efficacy Trends Positive in a Tough Population," Cantor Fitzgerald stated: "We are bullish on AKRO," and "We are positive on the upcoming readout in the F4 NASH population (NASH patients that have compensated cirrhosis)." But the analyst's opinion changed after the October 10, 2023 Call. As Cantor Fitzgerald commented in its post-readout report titled "Takeaways from Management Conversation Post F4 NASH Miss; Thoughts on the Stock From Here," the inclusion of cryptogenic cirrhotics in

SYMMETRY "was a surprise to us and most investors," and a "controversy" that may have negatively affected the trial:

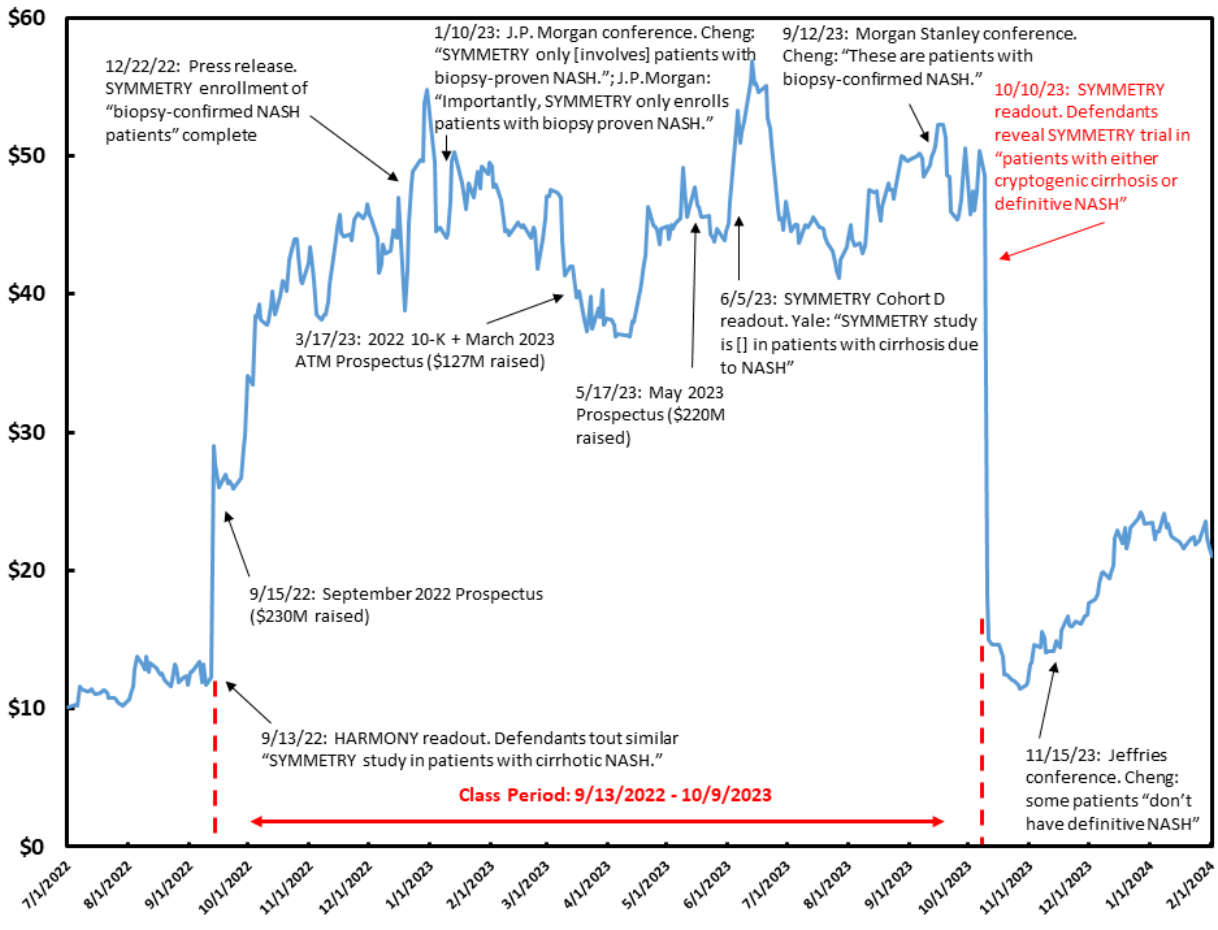
> **2) Cryptogenic NASH population vs. Definitive NASH:**
>
> - What's the ***controversy***: SYMMETRY trial included ~15-25% of patients with cryptogenic NASH (rest were definitive NASH), ***which was a surprise to us and most investors***. Cryptogenic NASH patients are more advanced, but don't satisfy typical NASH trial criteria (they score 0 on steatosis).
> - These patients were included in the primary endpoint but excluded from NASH resolution as ***they don't have definitive NASH.***
> - Treatment effect for EFX is little worse in cryptogenic NASH relative to definitive NASH, which we think ***may have negatively affected trial results as a few percentage points of efficacy benefit in EFX favor would have led to statistical significance***.
>
> **Cantor insight**: The baseline liver stiffness by VCTE in the Phase 2B SYMMETRY trial at ~24-25 looks more severe than 20-22 in other F4 trials, ***which may have been driven by cryptogenic NASH patients***.

80. Similarly, on October 11, 2023 H.C. Wainwright issued a report titled "Surprise Miss on 36-Week Fibrosis Improvement in Cirrhotic NASH Complicates the Path Forward; PT to $40." The report, which described Akero's inclusion of cryptogenic cirrhotic patients as a confusing decision that "likely impacted the statistical powering of the [SYMMETRY] study significantly[,]" stating:

> **Here's what we disliked or confused us about SYMMETRY.** ***Why cryptogenic cirrhotics? Why did the study entry criteria not exclude anyone but definitive NASH cirrhotics*** (NAS ≥ 3 with at least 1 for each of steatosis, inflammation and ballooning)? If requested by the FDA, why go up to the maximum 20% of study population (placebo was 26%)? ***In our view, this feature of the study needlessly introduces confounding risk, and may have played a part in missing the primary endpoint, in our view.***

81. In the days that immediately followed, analysts cut their price targets on Akero stock, with Morgan Stanley cutting its price target from $70 per share to $33 per share, Cantor Fitzgerald cutting its price target from $69 per share to $39 per share, H.C. Wainwright cutting its price target from $64 per share to $40 per share, J.P. Morgan cutting its price target from $62 per share to $41 per share, Evercore cutting its price target from $60 per share to $36 per share, and UBS cutting its price target from $83 per share to $39 per share.

82. These disclosures caused the Company's stock price to plummet nearly 70% on October 10, 2023, when Defendants revealed that, in fact, SYMMETRY included a different population of patients, *i.e.*, those with "cryptogenic cirrhosis," as reflected in the following chart:



83. Plaintiffs, on behalf of themselves and all other persons similarly situated, seek to recover damages resulting from Defendants' violations of the federal securities laws alleged herein.

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS ISSUED DURING THE CLASS PERIOD

A. Defendants Misleadingly Describe the Design of the SYMMETRY Trial

84. Throughout the Class Period, Defendants consistently represented to investors that Akero designed the SYMMETRY trial to study EFX in patients with cirrhosis ***due to NASH***.

85. Akero maintains a "Clinical Trials" page on its website. Prior to and throughout the Class Period, on that website, Defendants represented: "The Phase 2b SYMMETRY study is a multicenter, randomized, double-blind, placebo-controlled, clinical ***trial in biopsy-confirmed NASH patients*** with compensated cirrhosis (F4), Child-Pugh class A."

86. The "Clinical Trials" page on Akero's website, under the SYMMETRY section, also directs investors to "Read more at ClinicalTrials.gov." The ClinicalTrials.gov website is hosted by the National Library of Medicine and allows the public to look up information about drug trials as provided by trial sponsors or investigators. Before, during, and after the Class Period, the ClinicalTrials.gov page for the SYMMETRY trial published information provided by Akero about the trial titled "A Study of Efruxifermin ***in Subjects With Compensated Cirrhosis Due to Nonalcoholic Steatohepatitis (NASH)*** (Symmetry)."

87. Twelve "Study Record Versions" of the SYMMETRY trial are posted to the same ClinicalTrials.gov webpages for the SYMMETRY study.[9] Each of those 12 versions, under "Brief Summary," described the SYMMETRY trial as "a multi-center evaluation of efruxifermin (EFX) in a randomized, double-blind, placebo-controlled study ***in cirrhotic subjects with biopsy-proven F4 compensated NASH***."

88. The Class Period begins on September 13, 2022, when Akero filed a Form 8-K signed by Cheng (the "September 13, 2022 Form 8-K"). The September 13, 2022 Form 8-K discussed Akero's SYMMETRY study, describing it as "***a Phase 2b trial in biopsy-confirmed NASH patients with compensated cirrhosis***, Child-Pugh class A" and "***the SYMMETRY study in patients with cirrhotic NASH*** (F4 fibrosis, compensated)."

89. Also on September 13, 2022, Akero held an investor call to present data from the HARMONY trial and provide updates on the SYMMETRY trial (the "September 13, 2022 Call"). During the September 13, 2022 Call, Cheng and Yale both described the SYMMETRY study as

[9] Ten of the versions are dated before the Class Period: 9/2/21, 9/29/21, 12/23/21, 1/10/22, 2/15/22, 3/18/22, 5/20/22, 7/15/22, 8/10/22, and 9/8/22. Two are dated during the Class Period: 12/23/22 and 4/21/23.

"***our ongoing Phase 2b SYMMETRY study in patients with cirrhotic NASH***." Yale further stated:

> On the more immediate horizon, we are encouraged by the strength of our [HARMONY] histology results and what they mean for our ongoing Phase 2b SYMMETRY study in ***patients with cirrhotic NASH***. Based on today's results, we believe EFX has the potential to be the first investigational NASH drug to achieve statistically significant histological improvement in ***patients with cirrhotic NASH***.

90. Following the Company's September 13, 2022 Form 8-K and Call, several securities analysts issued reports indicating that the positive results in the HARMONY trial suggested positive results in the SYMMETRY trial, in particular because Defendants represented that both trials used patient populations with biopsy-confirmed liver damage due to NASH.[10] For example, on September 13, 2022, Canaccord Genuity issued a report titled "EFX hits on key FDA endpoints; we see strong read through to SYMMETRY Phase IIb data 2H23" emphasizing that like "[t]he HARMONY study . . . in patients with biopsy-confirmed F2-F3 stage of fibrosis due to NASH," the "***Phase IIb SYMMETRY study of EFX***" was being conducted "in F4 compensated ***cirrhotic NASH patients***."

91. After the September 13, 2022 statements concerning the HARMONY and SYMMETRY trials, Akero's stock price spiked, from $12.27 per share on September 12, 2022, to $29.05 per share on September 13, 2022, on massive volume of 49.7 million shares traded, up from just 678,600 shares traded on September 12, 2022.

92. Each of Defendants' statements set forth above in ¶¶85-89 concerning the design and composition of patients in the SYMMETRY trial was materially false and misleading when made as Defendants knew or deliberately disregarded and failed to disclose the following adverse facts:

(a) that approximately 20% of the patients enrolled in the SYMMETRY study did not have biopsy-proven compensated cirrhosis due to NASH; those patients had cryptogenic

[10] *I.e.*, F2-F3 fibrosis in the HARMONY trial, and F4 cirrhosis in the SYMMETRY trial.

cirrhosis, which is not the same as and should not be equated with "NASH cirrhosis" (*see* ¶¶158-159, 161);

(b) that it was "prespecified" in Akero's SYMMETRY trial design to include patients with cryptogenic cirrhosis, a fact Defendants have admitted to discussing with the FDA, confirming their knowledge of this patient subset (¶¶161-162);

(c) that it was further "prespecified" in Akero's SYMMETRY trial design to exclude patients with cryptogenic cirrhosis from the calculation of the NASH resolution secondary endpoints. The protocol's recognition of the need for separate data sets itself made clear to Defendants that the inclusion of cryptogenic cirrhotics was material to both the trial and the market (¶¶155-157, 161-162);

(d) that the SYMMETRY study did not align with FDA guidance for testing a drug in treating NASH cirrhotics because Akero had not ruled out potential causes of each patient's cirrhosis other than NASH (¶¶29, 77, 158);

(e) that, as a result of the inclusion of cryptogenic cirrhotics in the SYMMETRY study and in the calculation of the study's primary endpoint, Akero introduced a confounding factor into the study's design, materially influencing the study's potential results and increasing the risks that the study would fail to meet its primary endpoint (¶¶155-157, 160-161, 165-166); and

(f) that, as a result of (a)-(e) above, Defendants materially misrepresented the nature of the SYMMETRY trial, its usefulness in supporting any new drug application filed by Akero seeking approval for treatment of cirrhotic NASH patients, the likelihood that the SYMMETRY trial would be successful as measured by its primary endpoint, and the likelihood that EFX would become a commercial treatment for NASH cirrhotics.

93. Further, given that the Individual Defendants were involved in and personally oversaw the clinical trial protocol in sponsoring the SYMMETRY trial, and given Yale's position as CDO, and her signature on the BALANCED study protocol on behalf of Akero, it is reasonable to infer that she also approved the SYMMETRY study protocol on Akero's behalf (¶46). Moreover, the significance of the study to Akero's one product candidate, EFX, and therefore

Akero's business and prospects; Defendants' positions at Akero and responsibilities for speaking on Akero's behalf concerning the trial; and the number of times Defendants spoke specifically about the study and its design, indicate that the design and enrollment of SYMMETRY were known to Defendants. For the same reasons, the SYMMETRY trial design was core to the Company's operation.

B. Defendants Raise Millions from Investors to Support Ongoing Clinical Trials and Continue to Misrepresent SYMMETRY Design

94. On September 15, 2022, two days after the HARMONY readout, Akero filed the September 2022 Prospectus, pursuant to which the Company eventually sold over 8.8 million shares of Akero common stock at $26 per share, raising gross proceeds of approximately $230 million.

95. The September 2022 Prospectus reiterated the false statement that the SYMMETRY study was being conducted in patients with NASH-induced cirrhosis, stating:

> ***EFX is currently being evaluated in two Phase 2b clinical trials in patients with biopsy-confirmed NASH***: the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis) and ***the SYMMETRY study in patients with cirrhotic NASH*** (F4 fibrosis, compensated).

96. The September 2022 Prospectus further described the trial as: "***[O]ur ongoing Phase 2b clinical trial of EFX in patients with NASH who have cirrhosis (F4 fibrosis, compensated), known as the SYMMETRY study***."

97. In a section titled "Our Pipeline," the September 2022 Prospectus reiterated that the SYMMETRY study was evaluating EFX in patients with NASH-induced cirrhosis, stating:

> Our pipeline is anchored by EFX, a potential best-in-class FGF21 analog for treatment of NASH, if approved. We have one EFX program focused on patients with pre-cirrhotic NASH (F2-F3), which is supported by the HARMONY study, an ongoing Phase 2b clinical trial. ***We have a second EFX program focused on patients with cirrhotic NASH (F4, compensated), which is supported by the SYMMETRY study, an ongoing Phase 2b clinical trial***. These two programs align with FDA guidance published in 2018 and 2019, which recommends different regulatory approval pathways for patients with pre-cirrhotic and cirrhotic NASH.

98. The September 2022 Prospectus also incorporated by reference the 2021 10-K. The 2021 10-K further described the "***Phase 2b clinical trial of EFX in patients with biopsy-confirmed cirrhotic NASH*** (F4, compensated) for 36 weeks" as follows: "***The Phase 2b***

SYMMETRY study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial ***in patients with biopsy-confirmed cirrhotic NASH*** (F4 compensated), Child-Pugh class A."

99. The September 2022 Prospectus, again incorporating by reference the 2021 10-K, in a section titled "Risk Factors," purported to warn that identifying patients with NASH might be difficult, representing that the risk was particularly acute to Akero, because Akero was enrolling "***only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study***":

> Identifying and qualifying patients to participate in clinical trials is critical to our success. We may encounter delays in enrolling or be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study . . . . In particular, as ***a result of the inherent difficulties in diagnosing NASH*** and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. ***This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we are enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study and subsequent clinical trials***.

100. In a section titled "Summary of the material risks associated with our business," the September 2022 Prospectus further purported to warn that identifying patients with NASH "could" be difficult: "***Enrollment and retention of patients in clinical trials*** is an expensive and time-consuming process and ***could be made more difficult or rendered impossible by*** multiple factors outside our control, including ***difficulties in identifying patients with [NASH]*** [and] significant competition for recruiting such patients in clinical trials."

101. The September 2022 Prospectus and secondary offering had the intended effect, allowing Akero to continue operating through reporting the outcomes of the SYMMETRY trial the following year. For example, as Morgan Stanley confirmed in a November 4, 2022 report titled "3Q22 Earnings: Ph3 (F2-F3) Program Initiation Expected in 2023; Ph2b SYMMETRY (F4) Data on Track for 2H23": "Cash runway extended into 2025. Akero ended 3Q22 with $374M in cash and cash equivalents, which includes the ~$230M in gross proceeds from the recent public offering (September 19, 2022), and is expected to support operations into 2025 (vs 3Q24 previously)."

102. On November 4, 2022, Akero filed a Form 10-Q signed by Cheng and White (the "3Q22 10-Q"), reporting the Company's financial results for the third quarter of 2022 ending

September 30, 2022. The 3Q22 10-Q repeated the same false and misleading statements concerning the design of the SYMMETRY trial as the September 2022 Prospectus, including incorporating by reference the 2021 10-K which described it as a "clinical trial ***in patients with biopsy-confirmed cirrhotic NASH.***" ¶¶95-98.

103. The 3Q22 10-Q also repeated the same false and misleading risk warnings as the September 2022 Prospectus concerning the design of the SYMMETRY trial and purporting to warn that Akero faced risks in diagnosing and enrolling patients with NASH, including describing the "***inherent difficulties in diagnosing NASH***" as a "***risk [that] may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we are enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study***." ¶¶99-100.

104. Following the Company's September 2022 Prospectus and 3Q22 10-Q, analysts issued reports that reflected their understanding, based on Defendants' false and misleading statements, that the SYMMETRY trial was being conducted in patients with F4 cirrhosis due to NASH. For example, in a November 4, 2022 report titled "Straightforward Print into Fuller HARMONY Data at AASLD; 3Q Take and Model Update," J.P. Morgan stated: "As it relates to the ongoing SYMMETRY study (***EFX in F4 NASH***), the company remains on track for a top-line readout in 2H23." Similarly, H.C. Wainwright, in a November 7, 2022 report titled "3Q Recap; EFX Met Both Key NASH Endpoints in Phase 2b HARMONY Study; Cohort D Readout in 1H23; Raise PT to $64," stated that the analyst was looking to the "top-line data from the main SYMMETRY study with ***biopsy-confirmed NASH patients*** with compensated cirrhosis (F4), Child-Pugh class A in 2H23," to "further inform EFX's efficacy." On November 11, 2022, Canaccord Genuity issued a report titled "AASLD: there is more to Efruxifermin beyond fibrosis improvement" which also described the "ongoing Phase IIb SYMMETRY study of EFX in ***F4 NASH patients***."

105. Following the Company's September 2022 Prospectus and 3Q22 10-Q, analysts also discussed the importance of the SYMMETRY trial to the Company's future trials. For example, on November 17, 2022, Jefferies issued a report titled "AKRO, VTYX, IMCR - London

Bridges w/ CEOs" which stated in relevant part: "Using a separate parallel F4 study as the confirmatory study could accelerate timelines given these [patients] progress faster and F2/3 trial can be smaller. The decision to do this is all partly dependent on the ***F4 NASH trial readout Q4:23*** [SYMMETRY Phase 2b] and whether AKRO can show a solid treatment delta or effect there."

106. Between September 13, 2022 and November 4, 2022 Akero's stock price continued to trade at artificially inflated prices as high as $45.32 per share on October 25, 2022.

107. Each of Defendants' statements set forth in ¶¶95-100, 102-103 concerning the design and composition of patients in the SYMMETRY trial, and purporting to warn of the related risks in diagnosing and enrolling patients with NASH, was materially false and misleading when made as Defendants knew or deliberately disregarded and failed to disclose the following adverse facts:

(a) that, for all the reasons in ¶¶92-93 above, and contrary to Defendants' repeated misrepresentations, *inter alia*, that they were "only" enrolling patients with biopsy-confirmed NASH, Defendants "chose[]" to enroll, and in fact enrolled, patients with cryptogenic cirrhosis in the SYMMETRY trial;

(b) that, at the time Akero warned that it faced risks from the "inherent difficulties" in diagnosing and "***enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study***," Akero had already prespecified to enroll, and in fact had enrolled, patients with cryptogenic cirrhosis, which Defendants "***presumed*** [to be] ***secondary*** to NASH" (¶77, 158); and

(c) that, as a result of (a)-(b) above, Defendants' purported risk warnings that Akero might face difficulties identifying, diagnosing, or enrolling, *inter alia*, "only" patients with biopsy-confirmed cirrhosis due to NASH, were additionally false and misleading because the risk had already materialized.

C. Defendants Raise Further Millions from Investors to Support Ongoing Clinical Trials, Complete SYMMETRY Enrollment and Continue to Misrepresent SYMMETRY Design

108. On December 8, 2022, Defendants posted a press release on Akero's website announcing that, based on the previously reported HARMONY results, "Efruxifermin Granted FDA Breakthrough Therapy Designation for NASH." The press release falsely described: "An additional Phase 2b study, SYMMETRY, was initiated in July of 2021 to assess EFX in ***patients with compensated cirrhosis (F4) due to NASH***, Child-Pugh class A."

109. Following Akero's December 8, 2022 press release, analysts continued to rely on Defendants' false statements in reporting that SYMMETRY was a study conducted in patients with cirrhosis due to NASH. For example, on December 9, 2022, in a report titled "EFX Granted Breakthrough Therapy Designation in Less Than Three Months After Topline HARMONY Data; Affirm Buy" H.C. Wainwright stated that Akero's "ongoing Phase 2b SYMMETRY trial" was a study of "EFX in compensated ***cirrhotics (F4) due to NASH***." H.C. Wainwright also "set [its] preliminary risk-adjusted value of the market potential of EFX in ***cirrhotic (F4) NASH*** . . . at about $13 per share," more than a third of the current price listed in the report of $43.60.

110. On December 21, 2022, Defendants posted to Akero's website[11] a press release announcing that "Akero Therapeutics Completes Enrollment of Phase 2b SYMMETRY Study." Like the December 8, 2022 release, the December 21, 2022 release falsely described the Company's SYMMETRY trial: "The Phase 2b SYMMETRY main study is a multicenter, randomized, double-blind, placebo-controlled, clinical trial in ***biopsy-confirmed NASH patients*** with compensated cirrhosis (F4, Child-Pugh class A)."

111. Following Akero's December 21, 2022 press release, analysts continued to reflect their understanding that SYMMETRY tested EFX in patients with cirrhosis due to NASH. For example, on December 23, 2022, H.C. Wainwright issued a report titled "Phase 2b SYMMETRY

[11] Akero, *Akero Therapeutics Completes Enrollment of Phase 2b SYMMETRY Study and Announces Expected 2023 Milestones* (Dec. 21, 2022).

and Cohort D Complete Enrollment; Expecting Three Major Milestones in 2023; Affirm Buy" that noted "the main SYMMETRY study" was being conducted "in ***F4 NASH patients***."

112. On January 10, 2023, Cheng delivered a presentation at a JPMorgan Healthcare Conference during which he described SYMMETRY study in relevant part as follows:

> [B]ut really the biggest readout this year is in the F4 population. And for us, that's in the fourth quarter with SYMMETRY, with the patients with compensated cirrhotics. And people, I often get a question is why do we think this is going to be successful? I think the short answer is that we have proof-of-concept data, where we saw 58% of patients in a very, very small proof-of-concept study demonstrated either 1-stage improvement of fibrosis or NASH resolution after just 16 weeks of dosing. And I'll talk about that momentarily. I do want to remind everyone, this may look similar, but this is – like HARMONY, it's a randomized, double-blind, placebo-controlled trial. ***SYMMETRY only [involves] patients with biopsy-proven NASH, F4. And the primary endpoint of cirrhosis reversal, that is 1-stage improvement in cirrhosis. The similar secondary markers are being filed in the secondary endpoint, fibrosis markers and other liver injury markers. But the biggest difference is the duration***. It's not a 24-week study, but a 36-week one.

113. As part of his presentation at the January 10, 2023, JPMorgan Healthcare Conference, Cheng presented a slide deck that affirmed the statements he made about the SYMMETRY trial. One slide, titled "***SYMMETRY Trial Design: Cirrhosis Due to NASH (F4),***" listed ***only "F4 NASH"*** as a "Key Inclusion Criteria" for patients participating in the study.

114. Following the January 10, 2023 JPMorgan Healthcare Conference, analysts continued to report that SYMMETRY only enrolled patients with cirrhosis due to NASH. On January 10, 2023, the host of the conference, J.P. Morgan, issued its "Takeaways from JPM Healthcare '23," including reporting: "***Importantly, SYMMETRY only enrolls patients with biopsy proven NASH***."

115. On March 17, 2023, Akero filed its 2022 10-K signed by Cheng and White. The 2022 10-K described the SYMMETRY study in pertinent part as follows: "***[O]ur ongoing Phase 2b clinical trial of EFX in patients with NASH who have cirrhosis (F4 fibrosis, compensated), known as the SYMMETRY study***."

116. The 2022 10-K further stated in pertinent part that:

> ***EFX is currently being evaluated in two Phase 2b clinical trials in patients with biopsy-confirmed NASH***: a long-term follow-up period for the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis), for which we have reported recently results after 24 weeks of treatment, and the ***SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated)***.

117. The 2022 10-K further stated in a section titled "Our Pipeline" that the study was focused on "patients with cirrhotic NASH," stating in relevant part that:

> Our pipeline is anchored by EFX, a potential best-in-class FGF21 analog for treatment of NASH, if approved. We have one EFX program focused on patients with pre-cirrhotic NASH (F2-F3), which is supported by the HARMONY study, an ongoing Phase 2b clinical trial. ***We have a second EFX program focused on patients with cirrhotic NASH (F4, compensated), which is supported by the SYMMETRY study, an ongoing Phase 2b clinical trial.*** These two programs align with FDA guidance published in 2018 and 2019, which recommends different regulatory approval pathways for patients with pre-cirrhotic and cirrhotic NASH.

118. In providing an "Overview of EFX Clinical Development" the 2022 10-K reiterated that the SYMMETRY study was limited to patients with cirrhotic NASH, stating in relevant part that: "We have two active EFX programs supported by two ongoing, parallel Phase 2b clinical trials: the HARMONY study in pre-cirrhotic patients with F2-F3 fibrosis and ***the SYMMETRY study in patients with cirrhosis due to NASH*** (F4, compensated)."

119. The 2022 10-K further described the "***Phase 2b clinical trial of EFX in patients with biopsy-confirmed cirrhotic NASH*** (F4, compensated) for 36 weeks" as follows, stating in pertinent part: "***The Phase 2b SYMMETRY main study*** is a multicenter, randomized, double-blind, placebo-controlled, clinical trial ***in biopsy-confirmed NASH patients with compensated cirrhosis*** (F4, Child-Pugh class A)."

120. Notably, the 2022 10-K, in a section titled "Risk Factors," also purported to warn that identifying patients with NASH might be difficult, but removed the warning in the September 2022 Prospectus and 3Q22 10-Q that that risk was particularly acute to Akero because Akero was enrolling "***only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study***." Nevertheless, the 2022 10-K falsely and misleadingly purported to warn:

> Risks Related to Clinical Development
>
> ***Enrollment and retention of patients in clinical trials*** is an expensive and time-consuming process and ***could be made more difficult or rendered impossible by*** multiple factors outside our control, including ***difficulties in identifying patients with [NASH]*** [and] significant competition for recruiting such patients in clinical trials. . . ."
>
> Identifying and qualifying patients to participate in clinical trials is critical to our success. We may be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study . . . . In particular, ***as a result of the inherent difficulties in diagnosing NASH*** and the significant competition

> for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all.

121. Also on March 17, 2023, Akero filed with the SEC the March 2023 ATM Prospectus in connection with an at the market stock offering that ultimately raised at least $127 million in gross proceeds. The March 2023 ATM Prospectus incorporated the 2022 10-K by reference. The March 2023 ATM Prospectus thereby repeated the same false and misleading statements as the 2022 10-K, many of which were also made in the September 2022 Prospectus and 3Q22 10-Q, concerning the design of the SYMMETRY trial, including describing it as ***"the SYMMETRY study in patients with cirrhosis due to NASH*** (F4, compensated)." ¶¶115-119.

122. The March 2023 ATM Prospectus incorporated by reference the 2022 10-K, and repeated the same false and misleading risk warnings as 2022 10-K, many of which were also made in the September 2022 Prospectus and 3Q22 10-Q, purporting to warn that Akero faced risks in diagnosing and enrolling patients with NASH, including describing the "***inherent difficulties in diagnosing NASH***" as a risk that "could" affect Akero's SYMMETRY or other trials. ¶120.

123. Following the filing of the 2022 10-K and March 2023 ATM Prospectus, analysts reported that investors were paying close attention to the SYMMETRY Phase 2b results, and anticipating that positive results could enable Akero to get approval for accelerated timelines for Phase 3 trials of EFX and for getting EFX to market. For example, on March 17, 2023 in a report titled "Q4: Q in line; Paying Attention to Competitor Data Imminent and F4 Data Q4:23," Jefferies stated that "AKRO has a catalyst filled year," in particular with the SYMMETRY readout, stating in relevant part "***EFX F4 NASH biopsy data expected Q4:23 – we think this is the critical catalyst for the stock this year***." As Jefferies further explained (in a separate report it issued on March 17, 2023, titled "VTYX, AKRO, IMCR, IOVA: Miami Meetings, Tidbits in the Warm Sun," which compared Akero to competitors), Akero's ability to accelerate the Phase III trial and time to market "will depend on the outcome of the F4 study reading out late in Q4:23," *i.e.* the SYMMETRY Phase IIb readout.

124. Based on Defendants' representations, analysts also continued to report that the Phase IIb SYMMETRY trial was being conducted in patients with F4 cirrhosis due to NASH. For

example, a March 20, 2023, J.P. Morgan report titled "In-Line Quarter With Focus on Multiple SYMMETRY Readouts; 4Q Take and Model Update" described the "SYMMETRY study (EFX in F4 NASH)." So too a March 22, 2023 Evercore report titled "Overall positive readthru from ETNB" explained the "Efruxifermin P2b SYMMETRY data in cirrhotic (F4) NASH is coming in 4Q."

125. On March 29, 2023, Defendants posted to Akero's website[12] a press release titled "Akero Therapeutics Announces Positive End-of-Phase 2 Meeting with the FDA and SYNCHRONY Phase 3 Program for Efruxifermin in NASH." The release quoted Yale, who represented that the SYMMETRY trial was being conducted in "***patients with cirrhosis due to NASH***" and would inform ongoing discussions with the FDA, including as related to Akero's just-announced Phase III SYNCHRONY trials. The release stated in relevant part:

> "We are appreciative of the FDA's support and guidance and are pleased to have aligned on key features of our SYNCHRONY Phase 3 program, with further dialogue envisaged following readout of ***the Phase 2b SYMMETRY trial evaluating EFX in patients with cirrhosis due to NASH***," said Kitty Yale, chief development officer of Akero. "The strength of EFX's clinical profile reported to date in our Phase 2 studies gives us confidence in EFX's potential to be a best-in-class FGF21 analog for treating NASH, if approved . . . ."

126. Following the issuance of Akero's March 29, 2023 press release, analysts issued reports registering their increased confidence that the upcoming SYMMETRY readout would be positive and secure for Akero an accelerated timeline for its SYNCHRONY trials. For example, on March 29, 2023, Jefferies issued a report titled "Green light Phase III + our increasing confidence on big cirrhosis catalyst Q4," which noted "we're confident and also increasingly confident on F4 catalyst coming in Q4 this year [*i.e.* the SYMMETRY Phase IIb readout]." Jefferies further explained that "investors wanted reassurance and visibility into how AKRO can accelerate its path to market" and that the "details" of the Phase III "outcomes trial in an F4 population" were "pending SYMMETRY data Q4."

[12] Akero, *Akero Therapeutics Announces Positive End-of-Phase 2 Meeting with the FDA and SYNCHRONY Phase 3 Program for Efruxifermin in NASH* (Mar. 29, 2023).

127. Analysts also reported that the entire SYMMETRY trial was being conducted in cirrhotic NASH patients. For example, H.C. Wainwright, in a March 31, 2023 report titled "Positive EOP2 Meeting Leads to the SYNCHRONY Phase 3 NASH Program in Pursuit of the FDA's Alternative Pathway," stated: "As a reminder, the topline readout of the Phase 2b SYMMETRY trial (NCT05039450) of EFX ***in 182 compensated cirrhotic NASH patients*** (F4, Child-Pugh A) is expected in 4Q23."

128. One month later, on April 28, 2023, Akero filed its proxy statement with the SEC on Form DEF 14A. Under "2022 Performance Goals and Results" the Company listed as a goal "[e]nrollment of over 85% of our target enrollment for the Phase 2b SYMMETRY study in patients with ***cirrhosis due to NASH*** (F4, compensated)." No mention was made of enrolling cryptogenic patients. The Company determined that Akero's executives had met or exceeded that goal, and four others, stating: "In December 2022, the compensation committee determined that the Company had achieved 175% of its corporate goals for the fiscal year ended December 31, 2022. In light of such achievement, the board approved cash incentive bonuses for our named executive officers for fiscal year 2022 at 175% of target levels." As a result, for 2022, Cheng received a cash incentive award payment of $600,600, White received $316,400, and Yale received $310,800. In so reporting, the Company further indicated to investors that the Individual Defendants had successfully enrolled patients with cirrhosis due to NASH in the SYMMETRY study.

129. On May 15, 2023, Akero filed with the SEC a Form 8-K, signed by Cheng, that reported Akero's financial results for the first quarter of 2023 and provided a business update in a press release attached as an exhibit (the "May 15, 2023 Form 8-K"). The May 15, 2023 Form 8-K stated: "Results from the ***Phase 2b SYMMETRY study, evaluating treatment of patients with compensated cirrhosis due to NASH***, on track to be reported in the fourth quarter of this year."

130. Also on May 15, 2023, Akero filed with the SEC a Form 10-Q (the "1Q23 10-Q") signed by Cheng and White, reporting the Company's financial results for the first quarter of 2023 ending March 31, 2023. The 1Q23 10-Q incorporated by reference the 2022 10-K and thereby repeated the same false and misleading statements as the FY22 10-K and March 2023 ATM

Prospectus concerning the design of the SYMMETRY trial, including describing it as ***"the SYMMETRY study in patients with cirrhosis due to NASH*** (F4, compensated)." ¶¶115-119.

131. The 1Q23 10-Q also repeated the same false and misleading risk warnings as the 2022 10-K and March 2023 ATM Prospectus purporting to warn that Akero faced risks in diagnosing and enrolling patients with NASH, including describing the "***inherent difficulties in diagnosing NASH***" as a risk that "could" affect Akero's SYMMETRY or other trials. ¶120.

132. Following the filing of the 1Q23 10-Q, analysts continued to report that the Phase 2b SYMMETRY study was being conducted in patients with F4 cirrhosis due to NASH, and that the upcoming readout of the SYMMETRY trial remained the key driver of Akero's stock price and future prospects. For example, on May 15, 2023, Morgan Stanley explained in its report titled "1Q23 Earnings: Cohort D (GLP-1) and Key Ph2b SYMMETRY (F4) Data on Track for 2023" that Akero's stock was "overweight" and analysts saw "near-term opportunity for upside" for the stock from the SYMMETRY trial of "more advanced, cirrhotic (F4) NASH patients." Similarly, on May 16, 2023, Canaccord Genuity issued a report titled "SYMMETRY data readout on track in 4Q23; two Phase III trials to initiate in 2H23; PT increased to $59," which reminded investors that the "Phase IIb SYMMETRY trial in F4 NASH patients will report 36-week top-line data in 4Q23" and to "[r]ecall that the SYMMETRY study is being conducted in F4 NASH patients with compensated liver cirrhosis."

133. On May 17, 2023, Akero filed with the SEC the May 2023 Prospectus in connection with a secondary offering of common stock that ultimately sold over 5.2 million shares at $42 per share and raised $220 million in gross proceeds.

134. The May 2023 Prospectus repeated the same false and misleading statements as the 2022 10-K, March 2023 ATM Prospectus, and 1Q23 10-Q concerning the design of the SYMMETRY trial, including incorporating by reference the 2022 10-K which described it as ***"the SYMMETRY study in patients with cirrhosis due to NASH*** (F4, compensated)." ¶¶115-119.

135. The May 2023 Prospectus also repeated the same false and misleading risk warnings as the 2022 10-K, March 2023 ATM Prospectus, and 1Q23 10-Q purporting to warn that Akero faced risks in diagnosing and enrolling patients with NASH, including incorporating by

reference the 2022 10-K which described the "***inherent difficulties in diagnosing NASH***" as a risk that "could" affect Akero's SYMMETRY or other trials. ¶120.

136. Between September 13, 2022 and May 17, 2023 Akero's stock price continued to trade at artificially inflated prices as high as $54.88 per share on January 3, 2023.

137. Each of Defendants' statements set forth in ¶¶108, 110, 112, 113, 115-122, 125, 128-129, 130-131, 134-135 concerning the design and composition of patients in the SYMMETRY trial, and purporting to warn of the related risks in diagnosing and enrolling patients with NASH, was materially false and misleading when made as Defendants knew or deliberately disregarded and failed to disclose the following adverse facts:

(a) that approximately 20% of the patients enrolled in the SYMMETRY study did not have biopsy-proven compensated cirrhosis due to NASH; those patients had cryptogenic cirrhosis, which is not the same as and should not be equated with "NASH cirrhosis" (*see* ¶¶158-159, 161);

(b) that it was "prespecified" in Akero's SYMMETRY trial design to include patients with cryptogenic cirrhosis, a fact Defendants have admitted to discussing with the FDA, confirming their knowledge of this patient subset (¶¶161-162);

(c) that it was further "prespecified" in Akero's SYMMETRY trial design to exclude patients with cryptogenic cirrhosis from the calculation of the NASH resolution secondary endpoints. The protocol's recognition of the need for separate data sets itself made clear to Defendants that the inclusion of cryptogenic cirrhotics was material to both the trial and the market (¶¶155-157, 161-162);

(d) that during this period, Defendants completed enrollment of the SYMMETRY trial and thus knew not only the "prespecified" composition of the patient population in the trial but also the actual composition of patients enrolled (¶110);

(e) that the SYMMETRY study did not align with FDA guidance for testing a drug in treating NASH cirrhotics because Akero had not ruled out potential causes of each patient's cirrhosis other than NASH (¶¶29, 77, 158);

(f) that, as a result of the inclusion of cryptogenic cirrhotics in the SYMMETRY study and in the calculation of the study's primary endpoint, Akero had introduced a confounding factor into the study's design, materially influencing the study's potential results and increasing the risks that the study would fail to meet its primary endpoint (¶¶155-157, 160-161, 165-166);

(g) that, as a result of (a)-(f) above, Defendants had materially misrepresented the nature of the SYMMETRY trial, its usefulness in supporting any new drug application filed by Akero seeking approval for treatment of cirrhotic NASH patients, the likelihood that the SYMMETRY trial would be successful as measured by its primary endpoint, and the likelihood that EFX would become a commercial treatment for NASH cirrhotics;

(h) that, at the time Akero warned that it faced risks from the "inherent difficulties" in diagnosing and enrolling patients with NASH, Akero had already prespecified to enroll, and in fact had enrolled, patients with cryptogenic cirrhosis in the SYMMETRY study, which Defendants "***presumed*** [to be] ***secondary*** to NASH" (¶¶77, 158); and

(i) that, as a result of (a)-(h) above, Defendants' purported risk warnings that Akero might face difficulties identifying, diagnosing, or enrolling patients with biopsy-confirmed cirrhosis due to NASH were additionally false and misleading because the risk had already materialized.

D. As SYMMETRY Readout Approaches, Defendants' Continued Misrepresentations About the Trial Lead to Stock Highs and Increased Analyst Confidence

138. On June 5, 2023, Cheng, Yale, Rolph, and White delivered the "Phase 2b SYMMETRY Cohort D Data Presentation," during which they made a number of representations about the patient population of the main (*i.e.* not Cohort D) SYMMETRY trial. Cheng, for example, stated: "Akero's next key milestone is the readout of our Phase IIb ***SYMMETRY study in patients with compensated cirrhosis due to NASH***." Yale's description of the patients in the SYMMETRY study was no different:

> Cohort D is an expansion of ***the Phase IIb SYMMETRY study, a randomized double blind placebo controlled trial in patients with biopsy-confirmed NASH. Although the main SYMMETRY study is evaluating EFX in patients with***

cirrhosis due to NASH, Cohort D takes the EFX in patients with biopsy-confirmed fibrosis stage 1, 2 or 3.

139. Following the June 5, 2023 presentation, analysts continued to report that the main SYMMETRY trial was being conducted in patients with F4 cirrhosis due to NASH. For example, in a June 5, 2023 report titled "Cohort D Update Secures Combinability with, and Differentiation from, GLP-1s," J.P. Morgan noted: "On the next steps for EFX in NASH. ***The broader phase 2b SYMMETRY study in compensated (F4) NASH patients*** is anticipated in 4Q23."

140. On June 7, 2023, H.C. Wainwright's report titled "EFX + GLP-1 Combo Offers Substantial Benefit Over GLP-1s Alone, Exceeding Our Expectations; Raise PT to $64," similarly noted that the "***Phase 2b SYMMETRY main study in biopsy-confirmed NASH patients*** with compensated cirrhosis (F4, Child Pugh Class A) is fully enrolled." It also reported the funds raised pursuant to the March 2023 ATM Prospectus and the May 2023 Prospectus "provide for substantial cash balance and runway," which Akero expected to be "sufficient to fund its current operating plan into 2026."

141. On August 11, 2023, Akero filed with the SEC a Form 10-Q signed by Cheng and White (the "2Q23 10-Q"). The 2Q23 10-Q reported the Company's financial results for the second quarter of 2023 ending June 30, 2022. The 2Q23 10-Q repeated the same false and misleading statements as the 2022 10-K, March 2023 ATM Prospectus, 1Q23 10-Q, and May 2023 Prospectus concerning the design of the SYMMETRY trial, including incorporating by reference the 2022 10-K which described it as **"*the SYMMETRY study in patients with cirrhosis due to NASH*** (F4, compensated). ¶¶115-19.

142. The 2Q23 10-Q also repeated the same false and misleading risk warnings as the 2022 10-K, March 2023 ATM Prospectus, 1Q23 10-Q, and May 2023 Prospectus purporting to warn that Akero faced risks in diagnosing and enrolling patients with NASH, including incorporating by reference the 2022 10-K which described the "***inherent difficulties in diagnosing NASH***" as a risk that "could" affect Akero's SYMMETRY or other trials. ¶120.

143. Following the filing of the 2Q23 10-Q, analysts continued to report that the upcoming readout of results of from the SYMMETRY study of patients with F4 cirrhosis due to

NASH would likely be a significant positive for Akero. For example, on August 11, 2023, Jefferies issued a report titled "Q2 In-line and More Cash Added; Big Catalyst for ***F4 Cirrhosis NASH*** in Q4 Soon." As Jefferies explained, "F4 is the most unmet and severe form of NASH / w large market potential (arguably way better pricing dynamics too)." As a result, the analyst "continue[d] to feel positive . . . going into the Y[ear]E[nd] Phase IIb readout in F4 cirrhosis population and s[aw] potential strategic interest / scarcity value with big 50%+ stock move potential."

144. On August 14, 2023, H.C. Wainwright issued a report titled "2Q Recap; SYMMETRY Data in Cirrhotic Patients On Target in 4Q23; Initiations of SYNCHRONY Studies in 2H23; Affirm Buy," confirming the importance of the SYMMETRY study of 182 cirrhotic NASH patients to Akero's business. The report stated in relevant part:

> ***SYMMETRY is a key component of EFX's NASH regulatory path***. On August 11, Akero announced that Week 36 data readout from the Phase 2b SYMMETRY main study of efruxifermin (EFX) in ***adult cirrhotic NASH patients (F4, compensated)*** remains on track for 4Q23. Recall, the SYMMETRY main study (NCT05039450) ***enrolled 182 compensated cirrhotic NASH patients***, randomized to receive once-weekly subcutaneous dosing of EFX 28 mg, EFX 50 mg, or placebo. . . . Given that the FDA and EMA both regard fibrotic NASH and cirrhotic NASH as two wholly separate and distinct indications, we believe that Akero may opt to pursue the FDA's alternative NASH approval pathway if SYMMETRY top-line results are sufficiently positive. . . . As such, ***we regard SYMMETRY's Week 36 data readout in 4Q23 as a major milestone for EFX and Akero, as positive data would support EFX's advancement into a Phase 3 study in F4 NASH. Affirm Buy***.

145. On August 28, 2023, UBS initiated coverage of Akero and joined the chorus of analysts recommending that investors buy Akero. In their report titled "Akero Therapeutics Inc: Initiate Buy, $83: Game changer in NASH fibrosis?" UBS explained: "We initiate coverage of Akero . . . with a Buy rating and P[rice]T[arget] of $83," nearly double the reported current price of $46.91. UBS explained that its high valuation was based in significant part on the "potential for EFX in the NASH cirrhotic (F4) setting, which would significantly expand EFX's use. We see upside into Ph2b SYMMETRY data in 4Q (we think likely to hit)." UBS estimated a "market opportunity" of "$20B."

146. On September 12, 2023, at a Morgan Stanley Global Healthcare Conference, Cheng described the SYMMETRY trial in an investor presentation while again omitting information

concerning the inclusion of cryptogenic cirrhotics among the study's patient population, stating in relevant part:

> ***So this trial is a very straightforward Phase IIb trial***. It's 182 patients, randomized 1:1:1 to placebo 28 milligrams, of efruxifermin of 50 milligrams. ***These are patients with biopsy-confirmed NASH. That is that they have F4 NASH, they're cirrhotic*** and they're Child-Pugh Class A. These patients, also known as compensated cirrhotics, they're dosed for 36 weeks. And the primary endpoint is one stage improvement in fibrosis without worsening of NASH. And we're also looking at key secondary endpoints such as NASH resolution and a number of other biomarkers.

147. Following the September 12, 2023 Morgan Stanley Global Healthcare Conference, analysts continued to describe the SYMMETRY trial as being conducted in patients with F4 cirrhosis due to NASH. For example, in a September 12, 2023 report titled "Preview into F4 Cirrhosis NASH Data + Mgmt Meetings . . . Raise PT to $74," Jefferies described SYMMETRY as a "Phase IIb 36-week randomized, placebo-controlled, clinical study in ***biopsy-proven F4 compensated NASH patients***."

148. Following the September 12, 2023 conference, analysts also reported increasing confidence that the upcoming readout of SYMMETRY trial results would report positive outcomes including based on further conversations with Defendants. For example, on September 12, 2023, Jefferies issued a report titled "Preview into F4 Cirrhosis NASH Data + Mgmt Meetings. . . . Raise PT to $74," in which Jefferies reported hosting a dinner with Akero management and being confident in the upcoming SYMMETRY results for "EFX in F4 cirrhosis NASH [patients]," stating in relevant part:

> AKRO will report out an impt Phase II study for lead drug EFX in F4 cirrhosis NASH pts in October. ***We see a reasonably high probability of success and significant risk/reward if data are positive. We raise our PT from $60 to $74, given confidence*** and incl higher multiple assumptions, given M&A scarcity value if results are strong. ***We also hosted a packed mgmt dinner for investors, and came away incrementally positive***.

149. The September 12, 2023 Jefferies report further noted that the Company was already finished with the 36 week endpoint, and knew the dropout rates for participating patients. Jefferies was "incrementally more bullish" on Akero achieving statistically significant results:

> Study was originally planned for 150pts but was later over-enrolled by ~20% to 182 pts which should help with stronger powering and makes it easier to detect a stat sig benefit.

* * *

> Company is incrementally more bullish . . . .

* * *

> Company doesn't know about any blinded data for SYMMETRY but it's early finished and all sent to CRO. They are not aware of data but know dropout rates and no surprises there.

150. The September 12, 2023 Jefferies report also inserted the January 10, 2023 slide showing that the "F4 NASH" was the only "Key Inclusion Criteria" for participating in SYMMETRY.

151. The September 12, 2023 Jefferies report also modeled the likely impact to Akero's stock from the readout results, providing a useful comparison once Defendants reported actual results:

> We think stock could trade up 50% towards $75 if data are positive and clean – and it could continue to run higher depending on magnitude of benefit and also for pot'l strategic M&A value.
>
> If data are mixed/not stat sig – stock might go down 25-30% towards $30-35 if there is still a signal of activity and some optimism.
>
> If data are a full miss and negative – stock might go down 50% towards $25 but would be fundamentally undervalued at $1B on F2/3 indication alone which is still going to pivotal Phase III.

152. The analysts who issued reports in October prior to the October 10, 2023 SYMMETRY readout continued to reflect their understanding that the trial was in patients with cirrhosis (F4) due to NASH, connecting this population to the market opportunity for Akero and the importance of the readout to Company's success. An October 3, 2023 Cantor Fitzgerald report titled "Latest Investor Feedback & Poll Results on Different Efficacy Scenarios for AKRO F4 NASH Readout," explained "Akero's Phase 2B SYMMETRY trial data testing [] EFX [] in the ***F4 NASH population*** could come any day now," and further noted that "[m]ost investors (even NASH skeptics) agree that the F4 fibrosis segment . . . is the biggest commercial opportunity for a NASH drug." So too did H.C. Wainwright, in an October 5, 2023 report titled "Phase 2b HARMONY Dataset Provides Exhaustive Review of EFX; Phase 2b SYMMETRY Top-Line Readout This Month; Affirm Buy." In the report, H.C. Wainwright described "the Week 36 data

readout this month from the Phase 2b SYMMETRY (NCT05039450) main study of EFX in adult ***cirrhotic NASH patients*** (F4, compensated) as the next significant milestone for EFX and Akero. Affirm Buy."

153. Defendants' material misrepresentations and omissions caused Akero's stock price to trade at artificially inflated prices, including a Class Period high of $58.38 per share on June 13, 2023.

154. Each of Defendants' statements set forth in ¶¶138, 141-142, 146 concerning the design and composition of patients in the SYMMETRY trial was materially false and misleading when made as Defendants knew or deliberately disregarded and failed to disclose the following adverse facts:

(a) that, for all the reasons in ¶¶92-93, 137 above, and contrary to Defendants' repeated misrepresentations, *inter alia*, that they were enrolling patients with biopsy-confirmed NASH, Defendants "chose[]" to enroll, and in fact enrolled, patients with cryptogenic cirrhosis in the SYMMETRY trial, such that Defendants had materially misrepresented the nature of the SYMMETRY trial, its usefulness in supporting any new drug application filed by Akero seeking approval for treatment of cirrhotic NASH patients, the likelihood that the SYMMETRY trial would be successful as measured by its primary endpoint, and the likelihood that EFX would become a commercial treatment for NASH cirrhotics;

(b) that, at the time Akero warned that it faced risks from the "inherent difficulties" in diagnosing and enrolling patients with NASH, Akero had already prespecified to enroll, and in fact had enrolled, patients with cryptogenic cirrhosis in the SYMMETRY study, which Defendants "***presumed*** [to be] ***secondary*** to NASH" (¶¶77, 158); and

(c) that during this period, Defendants completed the 36-week endpoint of the SYMMETRY trial and thus knew not only the "prespecified" and actual composition of the patient population in the trial, but also the number and composition of patients who had made it through to the 36-week endpoint (¶149).

VIII. THE TRUTH IS REVEALED

A. Defendants Disclose SYMMETRY Trial Included Patients that Did Not Have Cirrhosis Due to NASH

155. Before the market opened on October 10, 2023, Akero filed with the SEC a Form 8-K, signed by Cheng, that attached a related press release and slide presentation as exhibits, in which the Company announced the results of the Phase 2b SYMMETRY trial (the "October 10, 2023 Form 8-K"). The trial's primary efficacy endpoint was the proportion of patients who achieved ≥ 1 stage improvement in fibrosis and no worsening of NASH, based on liver biopsies collected at week 36 versus baseline. The press release attached to the October 10, 2023 Form 8-K attempted to gloss over the fact that the SYMMETRY study had failed to meet its primary endpoint (as the results were not statistically significant) by calling the results a "trend" instead. The October 10, 2023 Form 8-K stated in relevant part:

> Akero Therapeutics, Inc. . . . a clinical-stage company developing transformational treatments for patients with serious metabolic disease marked by high unmet medical need, today reported a 36-week analysis of SYMMETRY, a 96-week Phase 2b study evaluating the efficacy and safety of its lead product candidate efruxifermin (EFX) ***in patients with compensated cirrhosis (F4) due to nonalcoholic steatohepatitis (NASH)***.
>
> ***A trend was observed for the primary endpoint of fibrosis improvement at 36 weeks, with 22% and 24% of the 28mg and 50mg EFX-treated groups, respectively, experiencing at least a one-stage improvement in liver fibrosis and no worsening of NASH, compared with 14% for placebo***. In addition, 4% of patients in each of the EFX-treated groups experienced a three- or two-stage fibrosis improvement without worsening of NASH – from compensated cirrhosis (F4) to F1 or F2, compared with 0% for placebo.

156. The October 10, 2023 Form 8-K further attempted to minimize the impact of the study's disappointing primary endpoint results by highlighting the statistically significant results in certain of the trial's secondary endpoints, most importantly NASH resolution, stating in pertinent part as follows:

> Statistically significant rates of NASH resolution in 63% and 60% of patients at week 36 were observed for the 28mg and 50mg EFX-treated groups, respectively, compared with 26% for placebo, representing the highest response rates reported to date for NASH resolution in this patient population. Statistically significant improvements were also observed for both EFX groups in non-invasive markers of liver injury and fibrosis, insulin sensitization and lipoproteins.

157. Tellingly, when calculating the placebo arm for the primary endpoint, Defendants listed 57 patients as being in the placebo arm's data set, whereas when Defendants calculated the number of patients in the placebo arm of the secondary endpoints for NASH resolution, Defendants only listed 46 patients as being in the placebo arm. This 11-patient discrepancy in the placebo arm stems from Akero's exclusion of cryptogenic patients when calculating NASH resolution, as reflected in footnote 1 of the press release, which notes in relevant part: "Source Data: Liver Biopsy Analysis Set (fibrosis improvement); ***Liver Biopsy Analysis Set (definitive NASH only) (resolution of NASH*** and combined endpoint)."

158. Also that morning, Akero held the October 10, 2023 Call with investors to discuss the SYMMETRY trial's results led by the Individual Defendants. During the October 10, 2023 Call, Defendants confirmed what they previously concealed from investors regarding the makeup of the patient population in the SYMMETRY trial. In her prepared remarks, Yale explained the discrepancy in pertinent part as follows:

> [G]ood morning, everybody. I'd like to begin with a review of the design of the SYMMETRY study, which is shown on Slide 6.
>
> The SYMMETRY study is a Phase IIb randomized, double-blind, placebo-controlled, multicenter dose-ranging trial. ***All patients had*** biopsy-proven compensated cirrhosis fibrosis Stage 4 due to definitive NASH ***or cryptogenic cirrhosis, presumed secondary to NASH***.
>
> ***Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population***.
>
> * * *
>
> This study enrolled patients with advanced liver disease, ***including patients with either cryptogenic cirrhosis or definitive NASH. The analysis set for NASH resolution endpoints excluded those with cryptogenic cirrhosis who didn't meet definitive NASH at baseline.*** That is the NAFLD activity score of greater than equal to 3, with a score of at least 1 in each of the components of steatosis, ballooning and inflammation.
>
> Consequently, the analysis set for NASH resolution is [comprised] of 126 patients, with 46, 38 and 42 patients, respectively, in the placebo 28 and 50 milligram dose groups.
>
> Cryptogenic cirrhosis is sometimes referred to as burn-type NASH, and is associated with advanced fibrosis and a higher level of risk in terms of liver decompensation or death.

159. During October 10, 2023 Call, Defendants also made repeated reference to the slideshow attached to the October 10, 2023 Form 8-K. The slideshow contained the same slide titled "SYMMETRY Trial Design: Cirrhosis Due to NASH (F4)" as the January 10, 2023 slide. ¶77. But the October 10, 2023 slide had two significant additions to the "Key Inclusion Criteria" for the study. The first difference was that the January 10, 2023 slide list only "F4 NASH" as a criteria; the October 10, 2023 slide newly added "T2D or 2 or 4 components of metabolic syndrome" as a second criteria. The second difference is that the October 10, 2023 slide added a new footnote, which confirmed what Defendants told investors during the October 10, 2023 Call, specifically that the study included patients with cryptogenic cirrhosis.

160. During the Question-and-Answer session of the October 10, 2023 Call, analysts pressed the Company on the inclusion of cryptogenic cirrhotics in the study, recognizing that the information was new and that the inclusion of these patients was a confounding factor in the results. For example, a J.P. Morgan analyst asked:

> And then, this potential for cryptogenic NASH, I think, is a new variable in thinking about the context of an F4 study. I guess, what's sort of – to the extent there are – are there any measures that could be tak[en] in a Phase III program to sort of ***reduce their participation and perhaps get a clearer signal***?

161. Cheng replied by acknowledging the different risk profile for patients with cryptogenic cirrhosis, stating: "In terms of cryptogenic cirrhosis, I think these patients represent a part of the cirrhotic spectrum . . . and I think we've – and in consultation with the FDA, have chosen to limit the patients to about 20% of the population." Cheng also acknowledged that Akero might need to remove cryptogenic patients from a Phase III trial, responding: "And I think [removing cryptogenic patients is] something we may consider to do. But of course, that's pending discussions with the agency, which we haven't had."

162. Similarly, an Evercore analyst asked, "[W]as it prespecified to take out the cryptogenic NASH patients?" and, when she did not get a direct answer from Cheng, again "And then just final question was on the cryptogenic cirrhotics. Was it prespecified to exclude them from some of the analysis? Or what was the plan there?" Yale then answered, admitting "***Yes, that was all prespecified***," thus confirming Defendants' knowledge or reckless disregard of the

true facts concerning the SYMMETRY study's patient population despite the fact that this information was contrary to what Defendants had told investors regarding the trial's design.

163. Following these disclosures, the price of Akero stock declined 62.6% from a close of $48.54 on October 9, 2023, to a close of $18.15 on October 10, 2023 on 31.9 million shares traded, up from just 631,600 shares traded on October 9, 2023. The stock price fell another 17% on October 11, 2023 to a close of $15.04 on 10.29 million shares traded.

164. In the days that immediately followed, analysts cut their price targets on Akero stock, with Morgan Stanley cutting its price target from $70 per share to $33 per share, Cantor Fitzgerald cutting its price target from $69 per share to $39 per share, H.C. Wainwright & Co. cutting its price target from $64 per share to $40 per share, J.P. Morgan cutting its price target from $62 per share to $41 per share, Evercore cutting its price target from $60 per share to $36 per share, and UBS cutting its price target from $83 per share to $39 per share.

165. Multiple analysts took particular issue with the previously undisclosed inclusion of cryptogenic cirrhotics in the trial. Cantor Fitzgerald, for instance, following the issuance of the October 10, 2023 8-K, but before the October 10, 2023 Call, issued a short report titled "Efruxifermin F4 NASH Trial Readout: Missed Primary But Efficacy Trends Positive in a Tough Population," stating that "[w]e are bullish on AKRO," including because "[w]e are positive on the upcoming readout in the F4 NASH population (NASH patients that have compensated cirrhosis)." But Cantor Fitzgerald's opinion changed after the October 10, 2023 Call. As the analyst noted in another report it issued later on October 10, 2023 titled "Takeaways from Management Conversation Post F4 NASH Miss; Thoughts on the Stock From Here," the inclusion of cryptogenic cirrhotics "***was a surprise to us and most investors***," and Cantor Fitzgerald described the inclusion of the cryptogenic cirrhotic patients as a "controversy" that may have negatively affected the trial. As Cantor Fitzgerald reported:

> **2) Cryptogenic NASH population vs. Definitive NASH:**
>
> - What's the ***controversy***: SYMMETRY trial included ~15-25% of patients with cryptogenic NASH (rest were definitive NASH), ***which was a surprise to us and most investors***. Cryptogenic NASH patients are more advanced, but don't satisfy typical NASH trial criteria (they score 0 on steatosis).

- These patients were included in the primary endpoint but excluded from NASH resolution as ***they don't have definitive NASH.***

- Treatment effect for EFX is little worse in cryptogenic NASH relative to definitive NASH, which we think ***may have negatively affected trial results as a few percentage points of efficacy benefit in EFX favor would have led to statistical significance***.

  Cantor insight: The baseline liver stiffness by VCTE in the Phase 2B SYMMETRY trial at ~24-25 looks more severe than 20-22 in other F4 trials, ***which may have been driven by cryptogenic NASH patients***.

166. Similarly, on October 11, 2023 H.C. Wainwright & Co. issued a research report titled "Surprise Miss on 36-Week Fibrosis Improvement in Cirrhotic NASH Complicates the Regulatory Path Forward; PT to $40." The report described Akero's inclusion of cryptogenic cirrhotic patients as a confusing decision that "likely impacted the statistical powering of the [SYMMETRY] study significantly." The report stated in relevant part:

> **Here's what we disliked or confused us about SYMMETRY.** ***Why cryptogenic cirrhotics? Why did the study entry criteria not exclude anyone but definitive NASH cirrhotics*** (NAS ≥ 3 with at least 1 for each of steatosis, inflammation and ballooning)? If requested by the FDA, why go up to the maximum 20% of study population (placebo was 26***%)***? ***In our view, this feature of the study needlessly introduces confounding risk, and may have played a part in missing the primary endpoint, in our view***.

(Emphasis in original and added.)

B. Post Class Period Disclosures Confirm that SYMMETRY Trial Did Not Include Only NASH Patients

167. Following the October 10, 2023 revelations, analysts continued to report on Akero's surprise inclusion of a "new" group of cryptogenic cirrhotic patients in the SYMMETRY trial. For example, on November 13, 2023, J.P. Morgan issued a report titled "Incrementally Supportive SYMMETRY Sub-Analysis at AASLD as Focus Shifts to 96-week HARMONY Readout; 3Q Takeaways & Model Update" because they "wanted to pass along some quick thoughts having had the chance to catch up with mgmt on the heels of 3Q results (net loss of $0.71 per share) and the company's follow up presentation of phase 2b SYMMETRY at AASLD."[13] J.P. Morgan noted the inclusion of a ***new subgroup*** that included patients with "cryptogenic cirrhosis

[13] The American Association for the Study of Liver Disease ("AASLD"), which held its annual The Liver Meeting on November 10-14, 2023.

at baseline." And on November 14, 2023, Morgan Stanley issued a report looking back at the SYMMETRY results titled "3Q23 Earnings: Ph3 SYNCHRONY Program Progressing on Track," in which it described Akero's inclusion of a "***new subgroup***" of "advanced cirrhotic patients (diagnosed ≥6mos before treatment or cryptogenic cirrhosis at baseline)."

168. On November 15, 2023, Akero presented at the Jefferies London Healthcare Conference. Following the presentation, Cheng answered questions from analyst attendees. In response to a question about Akero's 36-week SYMMETRY data interpretation in respect to the cryptogenic patients, Cheng stated:

> "I think, and Mike you're referring to when in F4, especially for cryptogenic patients, they have as what's known as burned-out NASH. Some of them don't have a score of one in the steatosis category, so ***they don't have definitive NASH***. So in that way, we didn't allow or claim credit for NASH resolution, and people who didn't have NASH to begin with."

Cheng's response indicated that the "people who didn't have NASH to begin with" were excluded from the secondary endpoint for "NASH resolution" – but not from SYMMETRY's primary endpoint, improvement of fibrosis.

169. On February 29, 2024, Akero filed with the SEC on Form 10-K its annual report for FY23. The Company's prior annual and quarterly reports and prospectuses had described SYMMETRY as: "[O]ur ongoing Phase 2b clinical trial of EFX in patients with NASH who have cirrhosis (F4 fibrosis, compensated), known as the SYMMETRY study." But the FY23 annual report newly added the same information Defendants disclosed on October 10, 2023: the "Phase 2b SYMMETRY study in patients with biopsy-confirmed compensated cirrhosis due to MASH (fibrosis stage 4, or F4, Child-Pugh class A) or ***cryptogenic cirrhosis presumed secondary to MASH***."[14]

IX. LOSS CAUSATION/ECONOMIC LOSS

170. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions regarding the composition of the patient in the SYMMETRY trial, in particular representing that that the trial composed entirely of patients with F4 cirrhosis

[14] *See supra* n.2 regarding the change in nomenclature from NASH to MASH.

due to NASH. *See* ¶¶84-154. These material misrepresentations and omissions caused Akero's stock price to trade at artificially inflated prices throughout the Class Period, including a Class Period high of $58.38 per share on June 13, 2023. When the truth regarding Defendants' misrepresentations and omissions became generally known, the price declined as the artificial inflation dissipated and Lead Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws. These disclosures of the truth include, but are not limited to, the following:

171. On October 10, 2023, Akero held a call with investors to discuss the SYMMETRY trial's results led by the Individual Defendants. During the October 10, 2023 Call, Defendants confirmed what they previously concealed from investors regarding the makeup of the patient population in the SYMMETRY trial. In her prepared remarks, Yale explained the discrepancy in pertinent part as follows:

> [G]ood morning, everybody. I'd like to begin with a review of the design of the SYMMETRY study, which is shown on Slide 6.
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> The SYMMETRY study is a Phase IIb randomized, double-blind, placebo-controlled multicenter dose-ranging trial. ***All patients had*** biopsy-proven compensated cirrhosis fibrosis Stage 4 due to definitive NASH ***or cryptogenic cirrhosis, presumed secondary to NASH***.
>
> ***Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population***.
>
> * * *
>
> This study enrolled patients with advanced liver disease, ***including patients with either cryptogenic cirrhosis or definitive NASH. The analysis set for NASH resolution endpoints excluded those with cryptogenic cirrhosis who didn't meet definitive NASH at baseline.*** That is the NAFLD activity score of greater than equal to 3, with a score of at least 1 in each of the components of steatosis, ballooning and inflammation.
>
> Consequently, the analysis set for NASH resolution is [comprised] of 126 patients, with 46, 38 and 42 patients, respectively, in the placebo 28 and 50 milligram dose groups.
>
> Cryptogenic cirrhosis is sometimes referred to as burn-type NASH, and is associated with advanced fibrosis and a higher level of risk in terms of liver decompensation or death.

172. During the Question-and-Answer session of the October 10, 2023 Call, analysts pressed the Company on the inclusion of cryptogenic cirrhotics in the study, recognizing that the

information was new and that the inclusion of these patients was a confounding factor in the results. For example, a J.P. Morgan analyst asked:

> And then, this potential for cryptogenic NASH, I think, is a ***new*** variable in thinking about the context of an F4 study. I guess, what's sort of – to the extent there are – are there any measures that could be tak[en] in a Phase III program to sort of ***reduce their participation and perhaps get a clearer signal***?

173. Cheng replied by acknowledging the different risk profile for cryptogenic cirrhotics, stating: "In terms of cryptogenic cirrhosis, I think these patients represent a part of the cirrhotic spectrum . . . and I think we've – and in consultation with the FDA, have chosen to limit the patients to about 20% of the population." Cheng also acknowledged that Akero might need to remove cryptogenic patients from a Phase III trial, responding: "And I think that's something we may consider to do. But of course, that's pending discussions with the agency, which we haven't had."

174. Similarly, an Evercore analyst asked, "[W]as it prespecified to take out the cryptogenic NASH patients?" and, when she did not get a direct answer from Cheng, again asked, "And then just final question was on the cryptogenic cirrhotics. Was it prespecified to exclude them from some of the analysis? Or what was the plan there?" Yale then answered, admitting "***Yes, that was all prespecified***," thus confirming Defendants' knowledge or reckless disregard of the true facts concerning the SYMMETRY study's patient population despite the fact that this information was contrary to what Defendants had told investors regarding the trial's design.

175. During the October 10, 2023 Call, Defendants also made repeated reference to the slideshow attached to the October 10, 2023 Form 8-K. The slideshow contained the same slide titled "SYMMETRY Trial Design: Cirrhosis Due to NASH (F4)" as the January 10, 2023 slide. ¶77. But the October 10, 2023 slide contained two significant additions to the "Key Inclusion Criteria" for the study. The first addition was that, while the January 10, 2023 slide list only "F4 NASH" as a criteria, the October 10, 2023 slide newly added "T2D or 2 or 4 components of metabolic syndrome" as a second criteria. The second difference is that the October 10, 2023 slide newly added a footnote, which confirmed what Defendants told investors during the October 10, 2023 Call, that "[a]ll patients had biopsy-proven compensated cirrhosis (fibrosis stage 4) due to

definitive NASH or cryptogenic cirrhosis presumed secondary to NASH. Subjects with cryptogenic cirrhosis were limited to approximately 20% of the total study population."

176. Following these disclosures, the price of Akero stock declined 62.6% from a close of $48.54 on October 9, 2023, to a close of $18.15 on October 10, 2023 on 31.9 million shares traded, up from just 631,600 shares traded on October 9, 2023. The stock price fell another 17% on October 11, 2023 to a close of $15.04 on 10.29 million shares traded.

177. In the days that immediately followed Akero's disclosure about the inclusion of cryptogenic cirrhotics in the SYMMETRY study, analysts cut their price targets on Akero stock, with Morgan Stanley cutting its price target by $37 from $70 per share to $33 per share, Cantor Fitzgerald cutting its price target by $30 from $69 per share to $39 per share, H.C. Wainwright & Co. cutting its price target by $24 from $64 per share to $40 per share, J.P. Morgan cutting its price target from by $21 from $62 per share to $41 per share, Evercore cutting its price target by $24 from $60 per share to $36 per share, and UBS cutting its price target by $44 from $83 per share to $39 per share.

178. Multiple analysts took particular issue with the previously undisclosed inclusion of cryptogenic cirrhotics in the trial. Cantor Fitzgerald, for instance, following the issuance of the October 10, 2023 8-K, but before the October 10, 2023 Call, issued a short report titled "Efruxifermin F4 NASH Trial Readout: Missed Primary But Efficacy Trends Positive in a Tough Population" stating that "[w]e are bullish on AKRO," including because "[w]e are positive on the upcoming readout in the F4 NASH population (NASH patients that have compensated cirrhosis)." But Cantor Fitzgerald's opinion changed after the October 10, 2023 Call. As the analyst noted in another report titled "Takeaways from Management Conversation Post F4 NASH Miss; Thoughts on the Stock From Here," issued later on October 10, 2023, the inclusion of cryptogenic cirrhotics "was a surprise to us and most investors," and Cantor Fitzgerald described the inclusion of the cryptogenic cirrhotic patients as a "controversy" that may have negatively affected the trial. As Cantor Fitzgerald reported:

2) Cryptogenic NASH population vs. Definitive NASH:

- What's the ***controversy***: SYMMETRY trial included ~15-25% of patients with cryptogenic NASH (rest were definitive NASH), ***which was a surprise to us and most investors***. Cryptogenic NASH patients are more advanced, but don't satisfy typical NASH trial criteria (they score 0 on steatosis).

- These patients were included in the primary endpoint but excluded from NASH resolution as ***they don't have definitive NASH.***

- Treatment effect for EFX is little worse in cryptogenic NASH relative to definitive NASH, which we think ***may have negatively affected trial results as a few percentage points of efficacy benefit in EFX favor would have led to statistical significance***.

  Cantor insight: The baseline liver stiffness by VCTE in the Phase 2B SYMMETRY trial at ~24-25 looks more severe than 20-22 in other F4 trials, ***which may have been driven by cryptogenic NASH patients***.

179. Similarly, on October 11, 2023 H.C. Wainwright & Co. issued a research report titled "Surprise Miss on 36-Week Fibrosis Improvement in Cirrhotic NASH Complicates the Regulatory Path Forward; PT to $40." The report described Akero's inclusion of cryptogenic cirrhotic patients as a confusing decision that "likely impacted the statistical powering of the [SYMMETRY] study significantly." The report stated in relevant part:

> ***Here's what we disliked or confused us about SYMMETRY. Why cryptogenic cirrhotics? Why did the study entry criteria not exclude anyone but definitive NASH cirrhotics*** (NAS ≥ 3 with at least 1 for each of steatosis, inflammation and ballooning)? If requested by the FDA, why go up to the maximum 20% of study population (placebo was 26%)? ***In our view, this feature of the study needlessly introduces confounding risk, and may have played a part in missing the primary endpoint, in our view***.

X. NO SAFE HARBOR

180. The statements alleged herein to be false and misleading are not subject to the protections of the PSLRA statutory safe harbor for forward-looking statements ("FLS") because they are either: (a) not forward looking; (b) subject to exclusion; or (c) not identified as forward looking or accompanied by meaningful cautionary language. 15 U.S.C. §78u-5(b)(2)(A).

181. Defendants are also liable for any false or misleading FLS pled because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and approved by an executive officer of Akero who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be

such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

XI. APPLICATION OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

182. At all relevant times, the market for Akero's common stock traded on an efficient market for the following reasons, among others:

(a) Akero common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) according to Akero's Form 10-K for the fiscal year ended December 31, 2022, Akero had more than 46 million shares outstanding as of March 17, 2023;

(c) as a regulated issuer, Akero filed periodic public reports with the SEC;

(d) Akero regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on national circuits of major newswire services, the internet, and other wide-ranging public disclosures;

(e) the Company was eligible to, and did, file an S-3 registration statement before the Class Period;

(f) the Company was covered by a significant number of analysts, as discussed above; and

(g) unexpected material news about Akero was rapidly reflected in and incorporated into the price for Akero's stock during the Class Period.

183. As a result of the foregoing, the market for Akero's stock promptly digested current information regarding Akero from publicly available sources and reflected such information in the price of Akero stock. Under these circumstances, all purchasers of Akero stock during the Class Period suffered similar injury through their purchases of Akero stock at artificially inflated prices, and a presumption of reliance applies.

184. A presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because Plaintiffs' claims are based, in significant part, on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Akero's business, operations, and guidance, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of Defendants' material misstatements and omissions set forth above, that requirement is satisfied here.

XII. CLASS ACTION ALLEGATIONS

185. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers or acquirers of the common stock of Akero during the Class Period (the "Class"). Excluded from the Class are Defendants, the officers and directors of Akero, at all relevant times, members of their immediate families, and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

186. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Akero stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there could be hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Akero or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

187. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful statements and conduct in violation of federal law that is complained of herein.

188. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

189. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the Defendants violated the Exchange Act as alleged herein;

(b) whether statements made by Defendants misrepresented or omitted material facts about the business, operations, and prospects of Akero, EFX, and the SYMMETRY trial;

(c) whether Defendants acted with scienter; and

(d) to what extent the members of the Class have sustained damages and the proper measure of damages.

190. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I
For Violation of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

191. Plaintiffs incorporate ¶¶1-190 by reference.

192. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

193. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Akero common stock during the Class Period.

194. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Akero common stock. Plaintiffs and the Class would not have purchased Akero common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' false and misleading statements and fraudulent scheme.

COUNT II
For Violation of §20(a) of the Exchange Act
Against All Defendants

195. Plaintiffs incorporate ¶¶1-194 by reference.

196. The Individual Defendants acted as controlling persons of Akero within the meaning of §20(a) of the Exchange Act. By reason of their positions with Akero and/or ownership of Akero common stock, the Individual Defendants had the power and authority to cause Akero to engage in the wrongful conduct complained of herein. Akero controlled the Individual Defendants and all of its employees. By reason of such conduct, Defendants are liable pursuant to §20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. determining that this action is a proper Class action, designating Plaintiffs as Lead Plaintiffs and certifying Plaintiffs as Class Representatives under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Lead Counsel;

B. awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. awarding such equitable, injunctive, or other relief as deemed appropriate by the Court.

XIV. JURY DEMAND

Plaintiffs demand a trial by jury.

DATED: September 24, 2024

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